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DISTRIBUTED MEDICAL DATABASE SYSTEM FOR REAL-TIME MONITORING OF THE HEALTH AND RISK EXPOSURE OF MILITARY RESEARCH STUDY VOLUNTEERS AT USARIEM

U S ARMY RESEARCH INSTITUTE
OF
ENVIRONMENTAL MEDICINE
Natick, Massachusetts

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Matthew J. Reardon, MAJ, MC
Donna Cardinal

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
US Army Research Institute of Environmental Medicine
Natick, MA 01760-5007

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This report describes a computerized medical database system designed to track the health and study related risk exposures and adverse incidents of soldiers participating as volunteer test subjects in USARIEM human-use research studies. This database system was implemented as an Oracle application on the USARIEM DEC VAX. The data collected at remote computer terminals are transmitted via modem and LAN to secure digital storage media at USARIEM. Database file access is controlled using methods to ensure test subject confidentiality and anonymity with regard to medical information. Only physician users are allowed access to medical details in the database. This database system was designed to improve the tracking of research study related risks and medical incidents as well as improve the coordination of medical care provided to test subjects by USARIEM physicians.

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A DISTRIBUTED MEDICAL DATABASE SYSTEM FOR REAL-TIME MONITORING OF THE HEALTH AND RISK EXPOSURE OF MILITARY RESEARCH STUDY VOLUNTEERS AT USARIEM

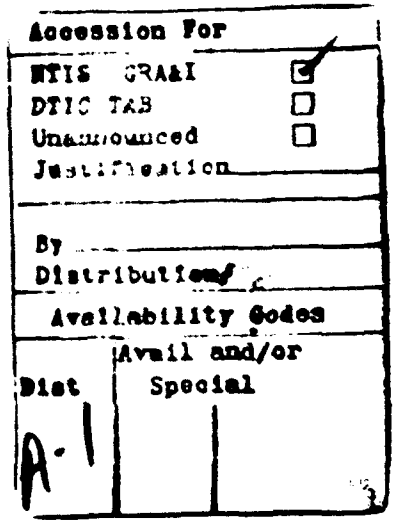
by

Matthew J. Reardon, MAJ-MC

and

Donna Cardinal

April 1994



U.S. Army Research Institute of Environmental Medicine

Natick, Massachusetts 01760-5007

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LIST OF ABBREVIATIONS

HURC	Human Use Review Committee
NRDEC	Natick Research Development and Engineering Center (US Army)
PC	Personal Computer
P^2NBC^2	Physiological and Psychological Effects of the Nuclear, Biological, and Chemical Environment and Sustained Operations on Systems in Combat (US Army Chemical School research program)
TS	Test Subject
TSCoord	Test Subject Coordinator
TSMDBS	Test Subject Medical Database System
TSMO	Test Subject Medical Officer
USAHC	US Army Health Clinic
USAMRDC	US Army Medical Research and Development Command recently renamed as: US Army Medical Research Development, Aquisition, and Logistics Command (USAMRDALC)
USARIEM	US Army Research Institute of Environmental Medicine

EXECUTIVE SUMMARY

This report describes a computerized medical database system designed to track the health and study related risk exposures and adverse incidents of soldiers participating as volunteer test subjects in USARIEM human-use research studies. It also facilitates the coordination of care among the numerous USARIEM medical monitors and NRDEC Test Subject Medical Officer.

The Test Subject Medical Database System (TSMDBS) establishes a computerized medical data collection structure, central data repository, on-line statistical analysis, and automatic report generating capabilities. The data are collected via computer terminals at locations where medical monitors and Test Subject physician supervise Test Subjects participating in environmental stress studies. The data collected at remote computer terminals are transmitted via modems and local area network lines to secure digital storage media at USARIEM.

Database file access is controlled using methods to ensure Test Subject confidentiality and anonymity with regard to medical information. Only physician users are allowed access to medical details in the database.

This system enables the USARIEM Commander, USARIEM Medical Advisor, USARIEM medical monitors, and the NRDEC Test Subject Medical Officer to have an on-line computer resource for real-time tracking of health indices and risk exposures of Test Subjects.

INTRODUCTION

The US Army Natick Research Development and Engineering Center (NRDEC) maintains a platoon of US Army enlisted soldiers who participate, on a voluntary basis, as test subjects (TS) in USARIEM human use research studies. The NRDEC Army health clinic provides initial and recurrent physical exams, study participation clearances, and primary care for members of the test subject platoon. USARIEM medical monitors (physicians) provide independent medical supervision to protect the health and well-being of the test subjects while they are participating in studies. Medical monitors ensure that study conditions and physiologic parameters do not exceed those explicitly approved by the research proposal review process and determine, on a daily basis, whether test subjects are in adequate physical and mental condition to participate in studies. They may remove test subjects from studies for any reason but do so particularly for signs of excessive stress or difficulty. Medical monitors provide on-site evaluation and treatment when necessary and document adverse study related medical incidents in test subjects' medical records. They also refer test subjects who are ill or have had an adverse study related incident to the NRDEC clinic Test Subject Medical Officer (TSMO) for further evaluation and disposition.

There are at least three principal problems with the current paper-based noncomputerized method of documenting and tracking the risk exposures and health of the Test Subjects that a distributed computer-based Test Subject Medical Database System (TSMDBS) can resolve:

1. Tracking study related incidents is labor intensive and cumbersome. It involves physically searching through, and collating, medical notes from test subject health records at the NRDEC health clinic as well as study related incident memos from medical monitors and principal investigators. Since these individuals work in different locations, collecting such data involves considerable time and effort. The fact that medical monitors must leave study sites and ambulate to the medical clinic to enter medical notes into the test subject medical records leads to underreporting of the study-related medical problems that are evaluated and resolved at the study site.

2. Because of frequent rotation of medical monitors during the course of a study, it is difficult for medical monitors to remain current about the health of the test subjects. Unless test subject medical records are reviewed daily by the medical monitors, it may not be known for example, that a test subject has been recently evaluated at the clinic for a condition that should exclude, at least temporarily, the test subject from further participation in a study. Or, it may not be known that a medical incident for which a test subject requires follow-up was recorded in the medical records by a previous medical monitor.

3. Statistical information for qualitative and quantitative assessment of risk exposures and health outcomes is not readily available. Determining which study related exposures are actually resulting in adverse outcomes is difficult and only sporadically summarized. The current unavailability of such information results in a less objective assesment of risk by the USARIEM Human Use Review Committee (HURC) than otherwise would be possible. Computerized tracking and reporting of study related Test Subject risk exposure and adverse incident data could be useful to members of the USARIEM HURC when reviewing research proposals. Current determinations of study related risks by HURC are primarily subjective or predicated on theoretical possibilities.

PRELIMINARY CONSIDERATIONS

The Test Subject Medical Database System (TSMDBS) requires the collection and processing of data and information pertaining to the health of the test subjects as well as a variety of supporting demographic and administrative data. This data is dynamic, often changing on a daily or weekly basis. For example, initial test subject medical evaluations or examinations as well as clearance status for continuing participation in USARIEM research studies must be updated each time there is a medical evaluation of a Test Subject's health.

Data relevant to the database are currently collected by the USARIEM medical monitors, the NRDEC Test Subject Medical Officer (TSMO), the NRDEC Test Subject Coordinator (TSCoord), and the USARIEM principal investigators.

Within a research proposal, a principal investigator (PI) describes the study schedule, conditions, and procedures. The extent to which a PI assesses the risks to TSs is reflected in the research proposal and the accompanying TS study participation consent form. The research proposal is submitted to the USARIEM Scientific Review Committee and USARIEM HURC for review. The HURC evaluates the proposal to determine whether it complies with guidelines and restrictions stated in the Type Protocol (USARIEM Type Protocol. 1992), whether all significant risks have been explicitly identified, whether some risks have been underestimated, and whether appropriate measures will be taken to mitigate the risks. In addition, the Committee ensures that the informed consent document explains the risks associated with the study in a manner that can be easily understood by a TS. Studies are categorized by HURC as either minimal or more than minimal risk. All study proposals and recommendations of the HURC are subsequently reviewed by the USARIEM Commander. Those study proposals considered to pose more than minimal risk to TSs are also forwarded to the next level of Command i.e., to the USAMRDC Human Use Review Office for further review and guidance.

When a research study is in progress, the principal investigator or designated research assistants record the daily chamber or environmental test conditions as well as TS responses in official laboratory notebooks. Medical monitors (military physicians at USARIEM) evaluate any significant changes in TS health status while research studies are in progress. The TSMO, at the NRDEC clinic, conducts the initial and periodic TS clearance examinations, evaluates TSs who come to sick call for nonstudy related problems, and provides backup medical support for TSs referred by a medical monitor for evaluation or follow-up of the consequences of a study related incident.

DESIGN AND DEVELOPMENT ISSUES

The forms, locations, and schedules utilized to collect demographic, medical, and administrative information about test subjects served as guides for suggesting the design of the computer-based data entry forms for the TSMDBS as well as to whom various data entry tasks should be delegated. After data have been accurately entered into the TSMDBS, the data can be processed by the use of form based queries or indexing, sorting, and data manipulation schemes using standardized Structured Query Language (SQL) commands to retrieve and/or synthesize the desired output. Reports can be structured to summarize TS risk exposures , health profiles, medical clearance status, and other useful information..

Confidentiality of medical data is an important consideration for medical databases. Not all data, however, require identical levels of protection. Reports that provide statistical summaries of TSs' health as groups or subgroups need not be as limited in access as reports that list details of patient-physician encounters or that include identifiers that could allow direct linkage of sensitive personal or medical information to a specific TS. Accordingly, the database was designed to provide a hierarchical access scheme based on database user types or classes. These classes include: the USARIEM Commander, USARIEM medical monitors and TSMO, PIs , TSCoord, and TSMDBS administrator or manager. As discussed subsequently, a TSMDBS Committee can provide a means for defining user types and controlling who is given access to the database.

Database access restrictions were implemented using a sequential security method. No users are permitted direct access to the database to copy or download medical database files. This is a basic access limiting safeguard. Another security measure is that the prospective database user must request access from the TSMDBS manager who determines whether that individual has a legitimate need to access the database (determined by a database committee as discussed below), whether that person is on the approved database access list, and, if so, to which class the user belongs. The database user is then given a computer account username and password to allow access to the database but only via menus that are tailored to the specific category of username. For example, the TSCoord is assigned an administrator class username. She/he may then enter and retrieve test subject

demographic information, study descriptions, risk exposure, as well as the most current list of test subjects according to whether they are cleared or not cleared for continuing participation in ongoing studies. On the other hand, her/his database menu does not permit access to medical data entry screens nor does it offer any options to generate reports containing medical details. Physician users (USARIEM Medical Advisor, medical monitors, and NRDEC TSMO) have the widest database access. The commander has wide access but not to detailed medical data. Customized periodic reports summarizing the health and risk exposure of test subjects as a group or subgroups without individual identifiers are available on the Commander's menu.

The system-user interfaces were designed for ease of use. An important design goal was to supplant paper data collection forms with comparable computer-based forms to facilitate a smooth and natural migration to the database method of recording the data. Avoiding the duplication of work load for those entering data into the TSMDBS was a major objective. This was considered to be an important feature for increasing the probability of user acceptance.

The functional and spatial interrelationships between the TSs and the principal database users are depicted in figure 1. These interrelationships served as a basis for clarifying the following components of the planning, implementation, and installation phases of the Test Subject Medical Database project:

1. Individuals who enter medical, demographic, and administrative data: Below are descriptions of the primary database users who must enter, or delegate their assistants to enter, data for the Test Subject Medical Database.

A. Test Subject Medical Officer (TSMO): this physician is located in the NRDEC clinic adjacent to USARIEM. He/she provides initial and periodic medical exams and determinations of fitness for research participation for permanent party and temporary duty (TDY) research volunteers. He/she also provides the majority of routine medical care for the NRDEC military test subject population and tracks care provided to them by off-post health care providers. If soldier volunteers become ill or injured while participating in a research

study, the medical monitor for the study sends the soldier to the NRDEC clinic for evaluation, treatment, and disposition by the TSMO. During the assessment and treatment of a TS, the TSMO obtains and records the following types of data :

- Medical history and physical exam
- Medical evaluation : chief complaint(s), history of present illness, pertinent past medical history, medications, allergies, vital signs, physical findings, laboratory results, results of other tests, assessment including diagnoses, as well as medications, other treatments, referral, and disposition.
- Cardiovascular risk assessment by collecting data about family history of early onset heart attacks or sudden death, cigarette smoking, serum cholesterol and glucose levels, blood pressure, abnormal cardiovascular symptoms, ECG results.
- Changes in Test Subject clearance status

B. Medical Monitors are military physicians assigned to USARIEM. Their primary responsibility is research, however, as part of their duties, they monitor the health and safety of Test Subjects while they participate in USARIEM research studies. It has been uncommon for one medical monitor to directly monitor a study every day from start to finish. This impairs the tracking and coherent management of TS medical problems. In the course of monitoring TSs, medical monitors obtain and record data pertaining to the assessment, treatments, disposition, and changes in research participation clearance status for TSs. The data elements involved in this process are similar to those described above for the TSMO.

C. Principal Investigators are responsible for all phases of a study. Their research proposals undergo rigorous internal reviews to ensure scientific merit and compliance with human use health and safety requirements and risk exposure limits. In developing a study protocol, the principal investigator defines the following data:

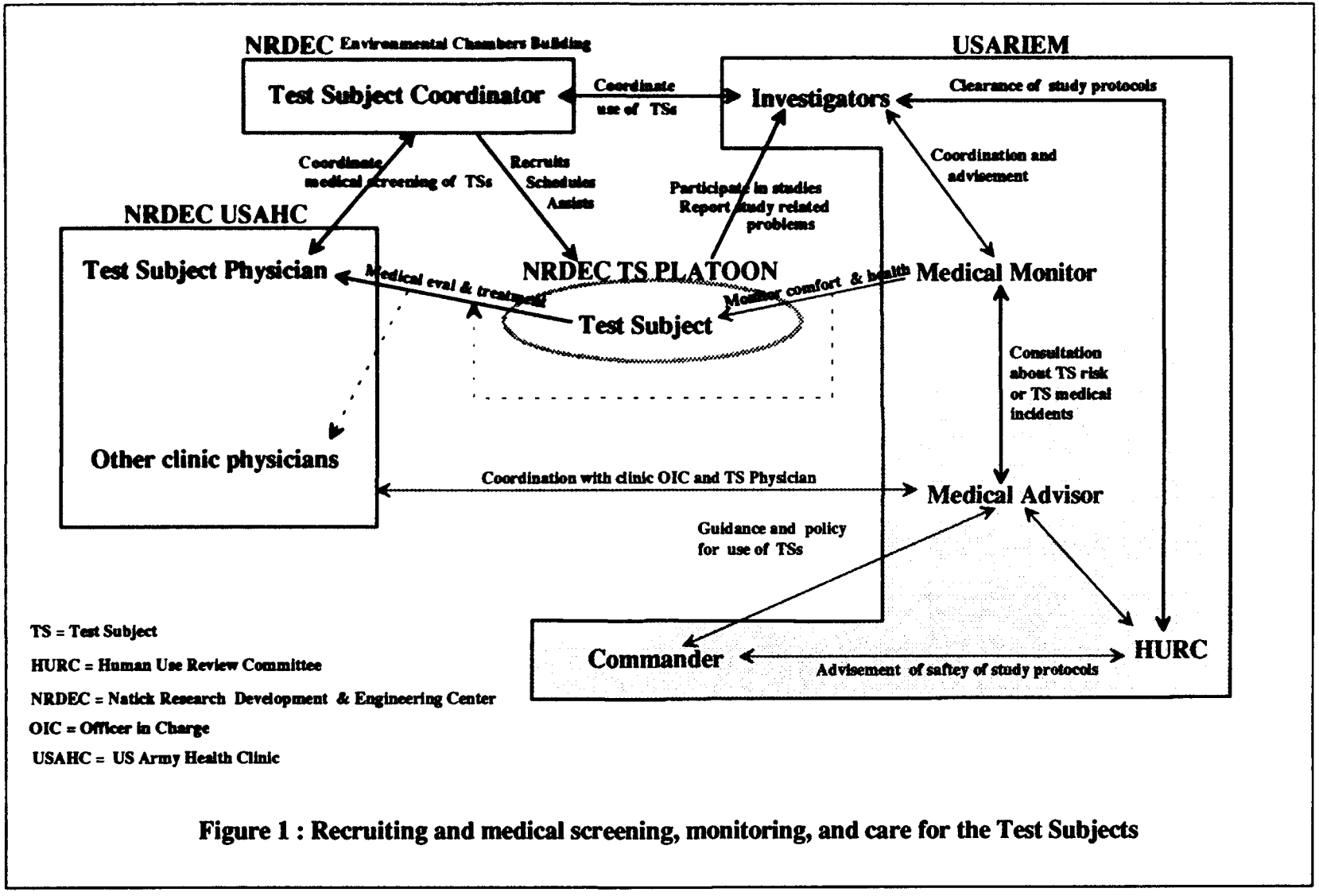


Figure 1 : Recruiting and medical screening, monitoring, and care for the Test Subjects

- Exceptions to type protocol.
- Number of test subjects.
- Schedule of research activities and procedures.
- Environmental parameters
- Use of medications.

D. Test Subject Coordinator (TSCoord) : The TSCoord is a civilian administrator who recruits and manages the assignment of the TSs to NRDEC and USARIEM research studies. The TSCoord collects basic demographic information about the TSs and develops quarterly schedules that assign TSs to various studies. The TSCoord receives requests for TSs from PIs. After the research studies are approved, the TSCoord then conveys to the PIs information about the specific TSs assigned to his/her study.

E. Research Programs and Operations Division, USARIEM: coordinates the research proposal clearance process. Personnel in this division maintain information for pending, active, and completed research studies in an archive of study related documents.

2. Database access sites: Perusal of figure 1 as well as more detailed review of the commonly used locations for USARIEM in-house research suggested that the TSMDBS be accessible from PCs or terminals located at the following sites:

- Medical Database Manager's office
- USARIEM PC User Center
- Commander's/XO's office
- Medical Advisor's office
- Chief Medical Monitor's office
- Test Subject Physician's office
- Clinic records office
- Test Subject Coordinator's Office
- Environmental chambers observation areas
- Water emersion observation area
- Altitude chamber observation area

3. **Prioritization of objectives:** Figure 2 illustrates a prioritized list of objectives for the TSMDBS. Such a prioritization scheme facilitates tradeoff analysis during the database planning and implementation stages. Development of database modules for obtaining and processing data to achieve the higher level objectives takes precedence over efforts to implement modules to achieve lower priority objectives. Elements of information for the database were selected for inclusion into the Test Subject Medical Database System based on an assessment of the usefulness of the data in supporting the main objectives of the system.

4. **Data Collection:** Obtaining information about the medical clearance status and health of TSs has relied primarily on verbal interfacing of medical monitors, TSMO, and PIs. This process is often time consuming and requires individuals to track each other's location so that the relevant data can be directly exchanged. The TSMDBS allows near instantaneous transmission, storage, and retrieval of such data by modem and wire or wireless local or wide area network (LAN or WAN).

5. **Database Management:** A TSMDBS management plan facilitates the efficient allocation and monitoring of resources required to design, implement, and maintain the database system as well as provides a continuing database quality assurance program. Such a plan delineates the composition and operational charter for a TSMDBS Development and Maintenance Committee. This Committee ensures that there is due consideration and reconciliation of competing opinions with respect to the design, implementation, and upgrades to the database. Figure 3 suggests a possible composition for such a committee as well as the interfaces with individuals and entities who use or contribute to the database.

Figure 4 illustrates steps in the Database Committee's responsibilities for database configuration management.

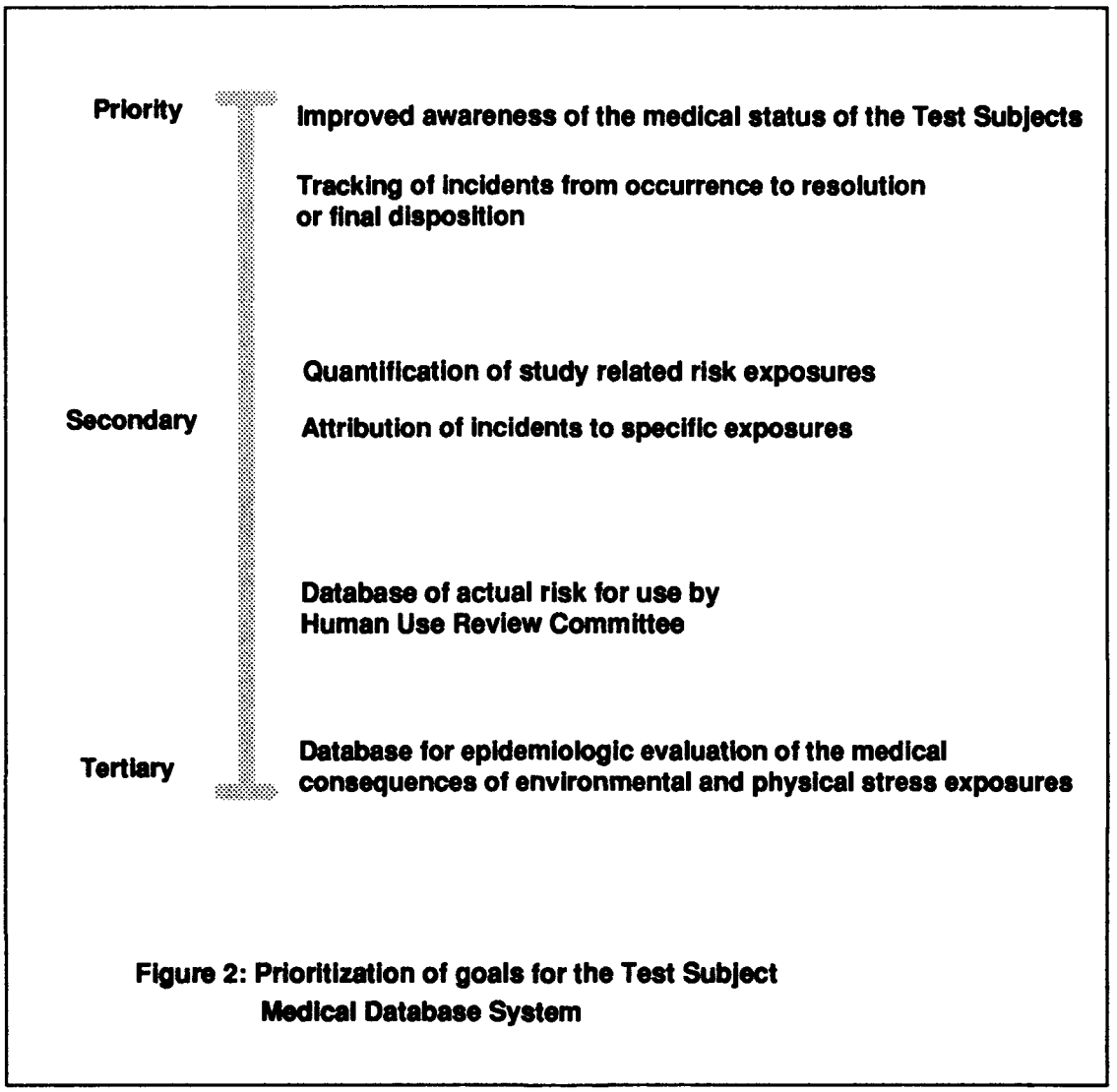


Figure 2: Prioritization of goals for the Test Subject Medical Database System

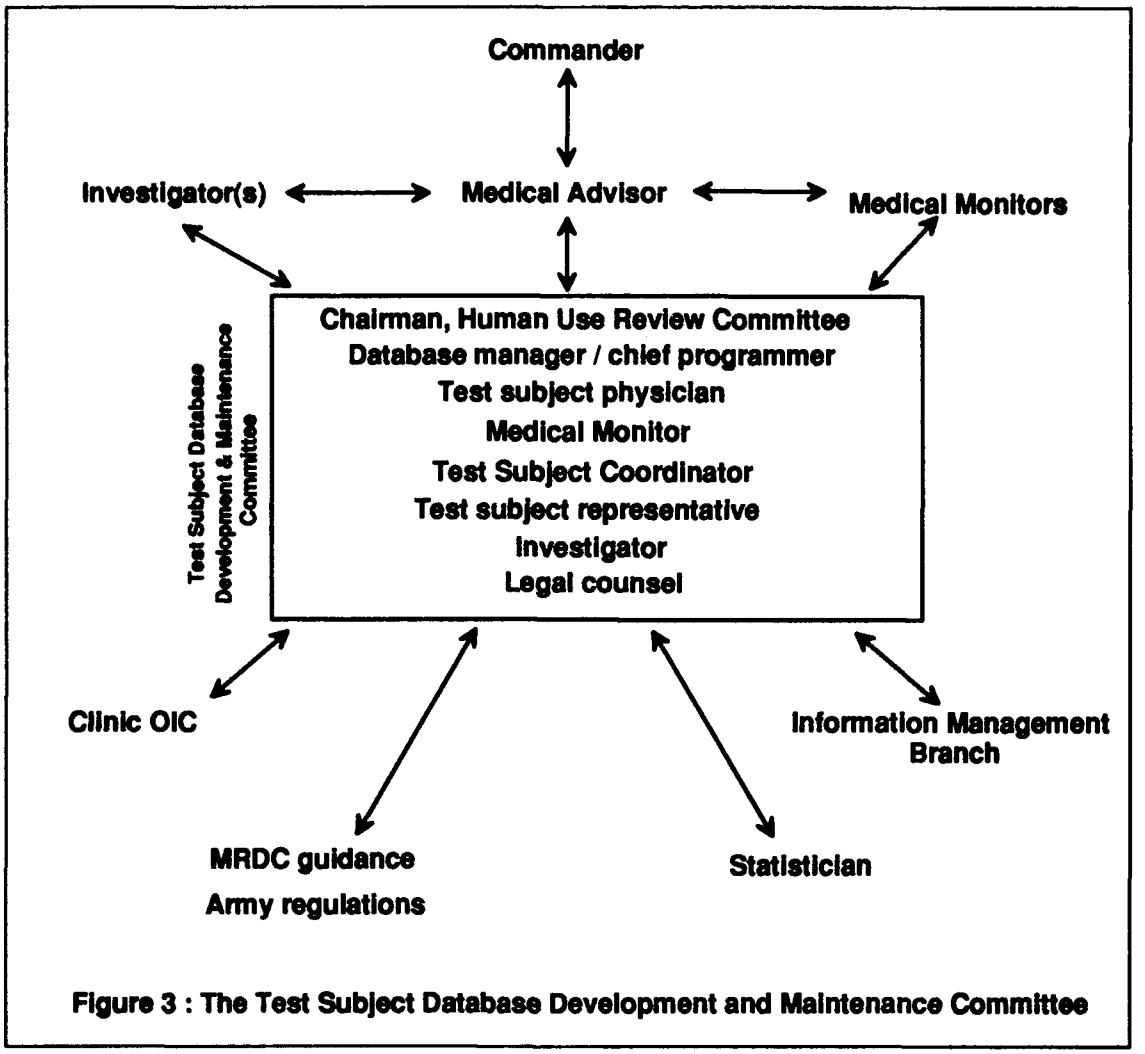


Figure 3 : The Test Subject Database Development and Maintenance Committee

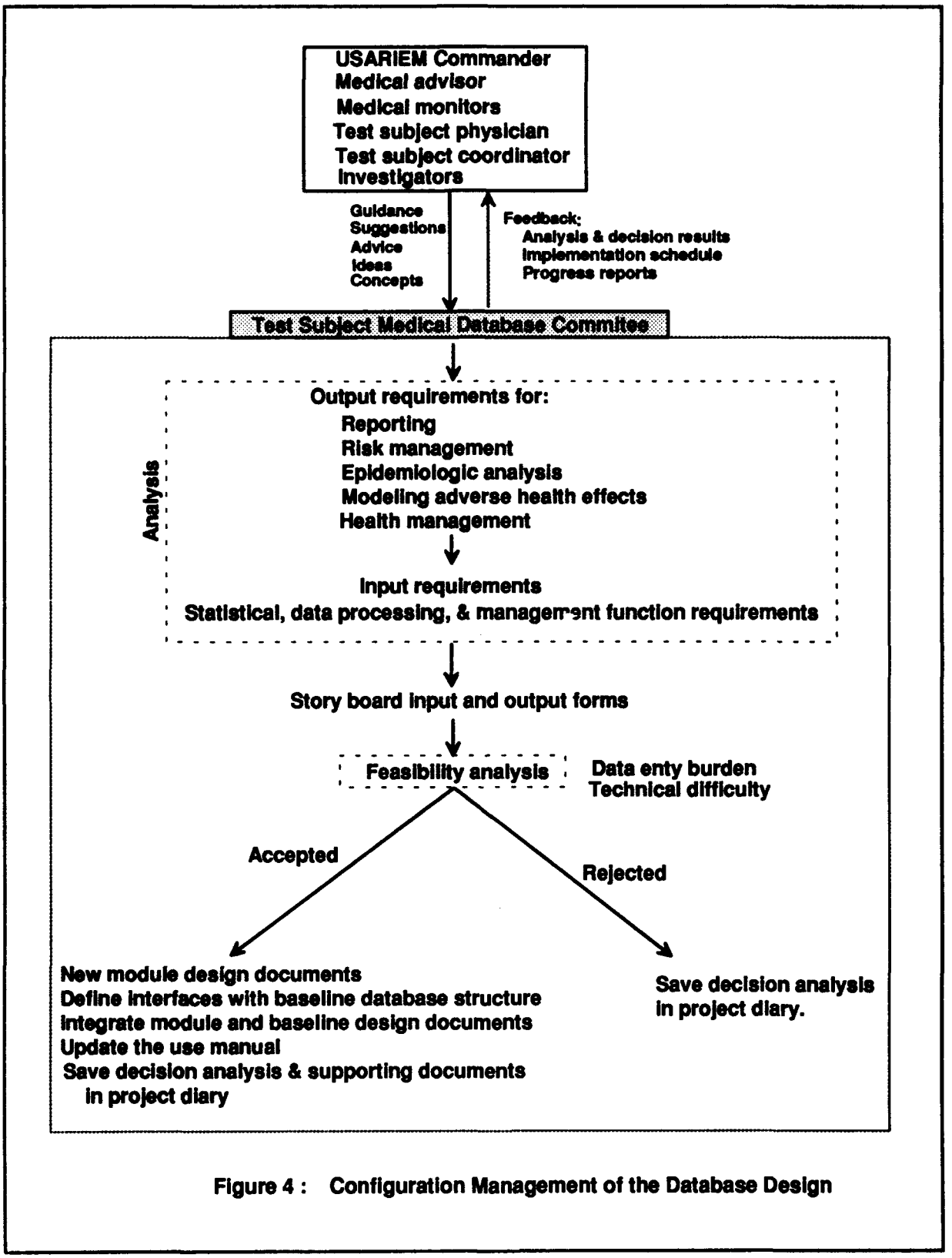


Figure 4 : Configuration Management of the Database Design

6. **Training the Database Users**: This aspect of implementing a distributed medical database system is a major determinant of its acceptance and ultimate success. Training requirements can often be decreased by designs that generate user friendly interfaces, on-line help facilities, and embedded tutorials. User training requires planning and scheduling, document development and maintenance, and feedback to determine its efficacy. Software user training requirements are dynamic. Initial training occurs as the system is first introduced and, subsequently, for new users. Abbreviated training sessions may be required at latter dates in conjunction with TSMDBS upgrades. Alternatively, changes associated with minor upgrades can be disseminated by memoranda or on-line messages.

7. **Enforcement of the Data Entry Assignments:** A database system that is easy to use and whose input/output requirements decrease work loads compared to paper-based data transactions will usually be accepted without troublesome resistance. Overt or passive refusals to comply with data entry responsibilities after training and an adequate period for learning how to use the database system may be an indicator that the new database system is decreasing productivity, is too slow or difficult to use, or is not perceived to be achieving the stated objectives. If this occurs, the situation should be investigated to determine the actual or perceived problems. The psychological basis of software rejection should be explicitly addressed. Individuals may refuse to enter necessary data because they do not understand the importance of the data to the overall functioning of the system, how others may depend on the data, or because they feel slighted for not having been included in the database design effort. After an investigation into the problem is completed, remedial actions should be taken. This might include additional training , modifications to the database interface to make it easier to use, or hardware upgrades to eliminated dataprocessing or transmission bottlenecks.

Candidate data elements that each type of TSMDBS user could enter into the system were determined from analysis of data fields in the paper forms utilized for data collection. The database data fields that were implemented are listed in Appendix A.

The relationships between the database tables, accessibility, and different types of database users are depicted in figures 5, 6, and 7.

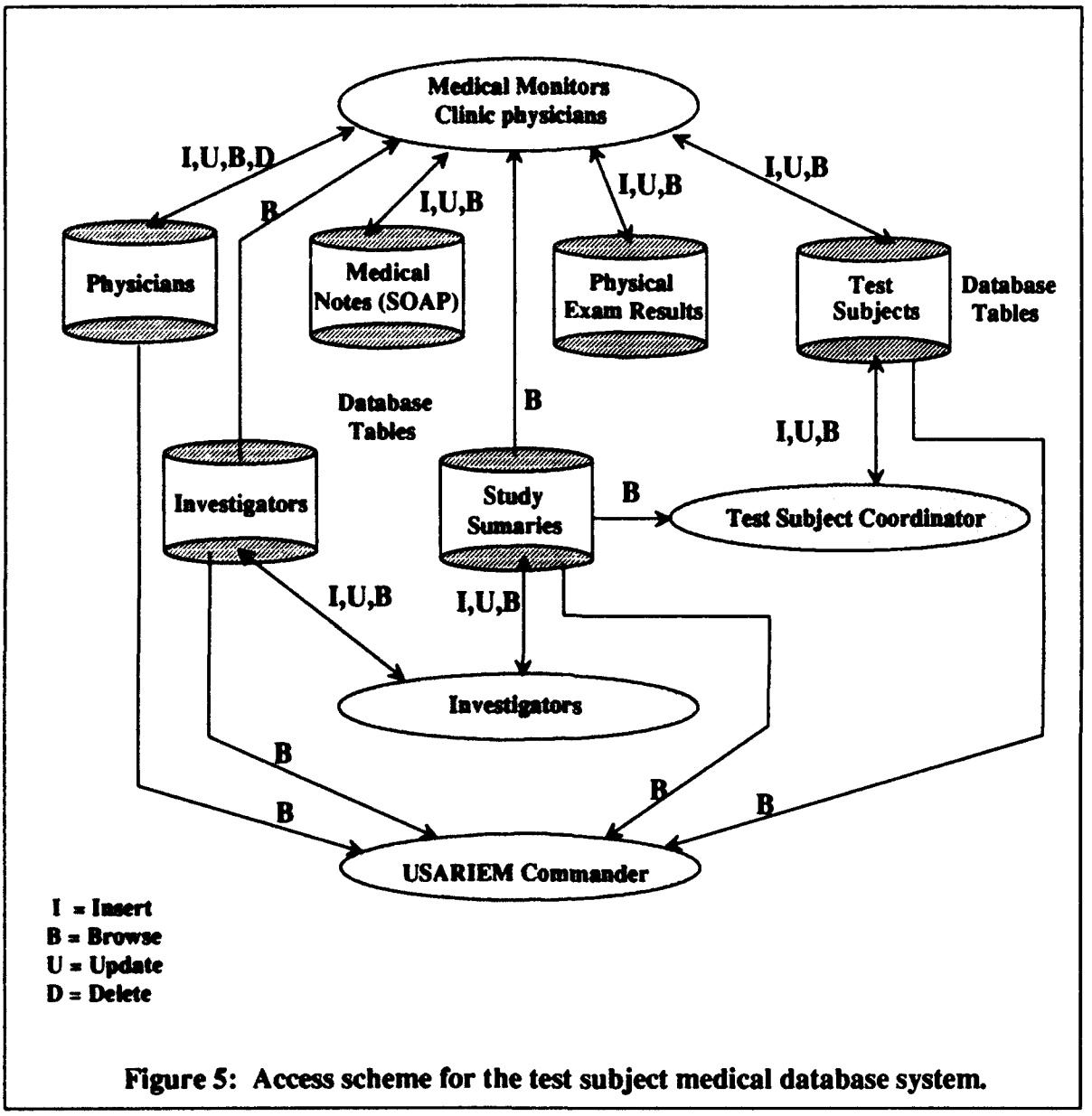
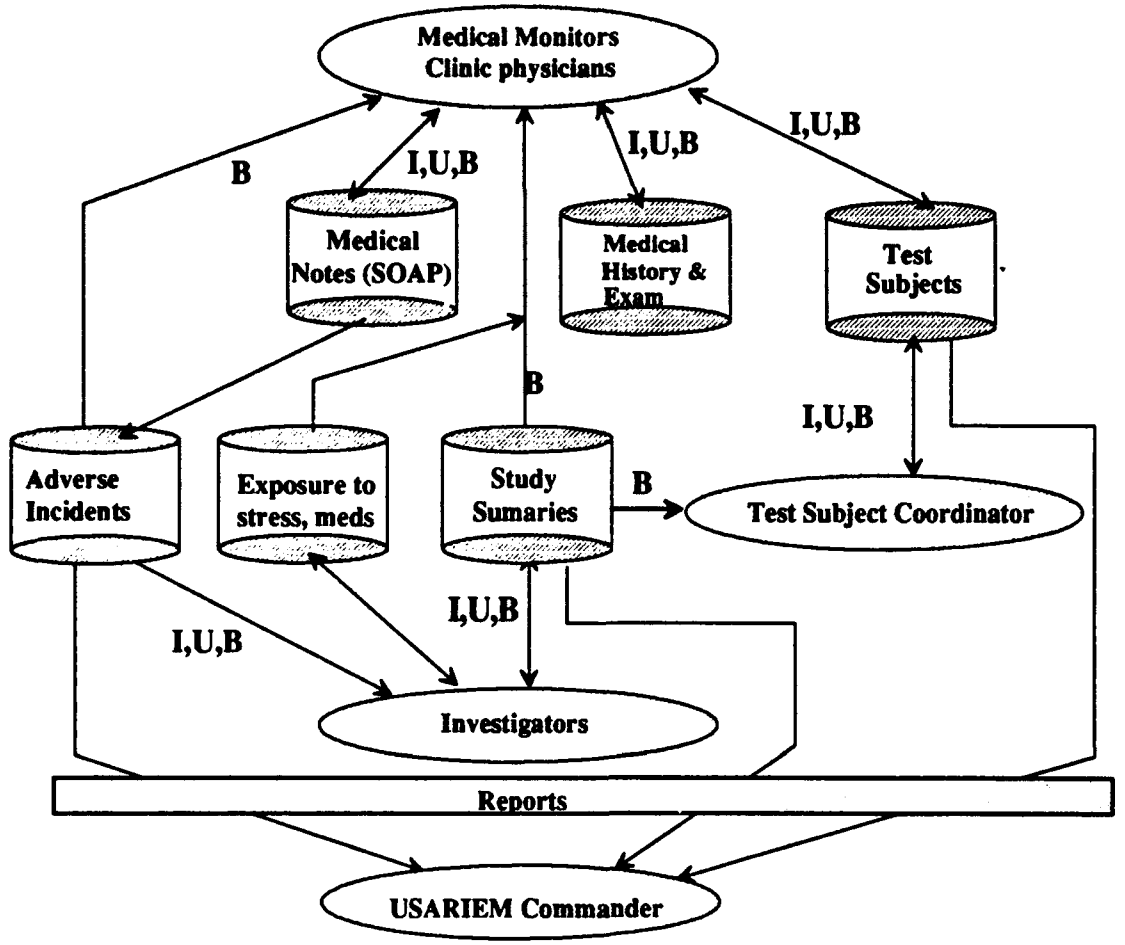


Figure 5: Access scheme for the test subject medical database system.

Figure 5 above illustrates that the database tables are organized in such a fashion as to isolate the confidential medical contents from other tables containing demographic data about the test subjects, information about the professional staff (medical monitors, clinic physicians, and principal investigators), as well as summary descriptive data for each human use research study.



B = Browse
U = Update
D = Delete
I = Insert

Figure 6: Access scheme for the risk and adverse incidents portion of the Test Subject medical database system.

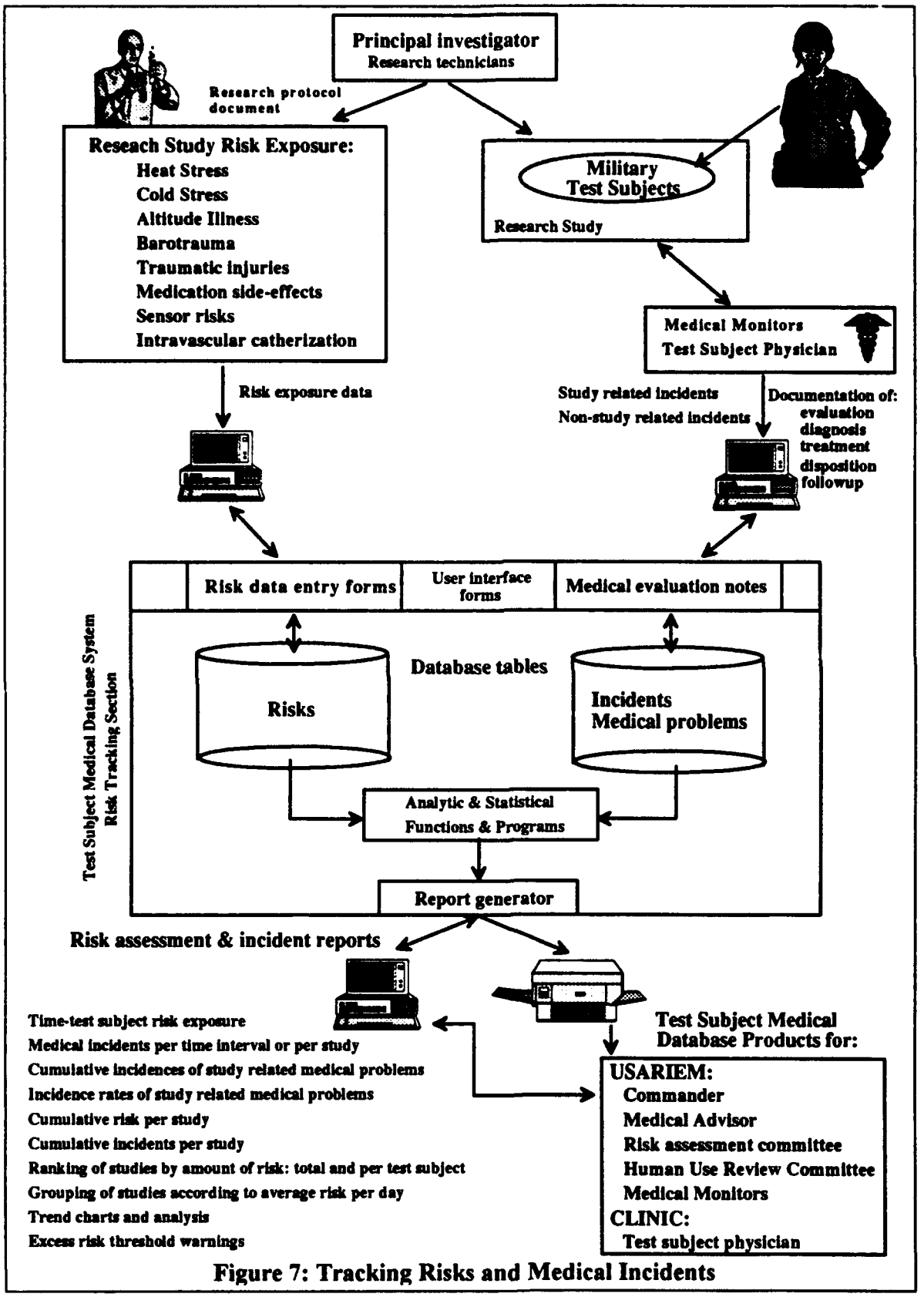


Figure 7: Tracking Risks and Medical Incidents

Users of the database system are indicated by the ovals. The legend indicates how the TSMDBS users are limited in their access to the contents in the different database tables. Figure 6 complements figure 5 by including the tables for risk exposure and adverse incident data.

Figure 6 also illustrates that the USARIEM Commander has access to the data in the various data tables via reports which can be selected from the Commander's report menu. The data for the Commander are provided in summary formats tailored to his/her specific requirements. TS anonymity, however, will be preserved and details from the medical portions of the database will not be directly available except to the physician users.

Figure 7 illustrates in greater detail the interrelationships between database users and the medical risks and adverse incidents portion of the database.

METHODS

SOFTWARE:

The TSMDBS was implemented with the Oracle Database Development System running on the Digital Equipment Corporation's (DEC) VAX/VMS operating system (Oracle Corporation, 1986). Oracle is currently one of the most prevalent Standard Query Language (SQL) database development systems (Perry and Lateer, 1989). It incorporates numerous features that permit the implementation of a large, complex, distributed database system.

Modem control and terminal emulation software is required to access the VAX-6510 via modem. There are numerous software packages available that provide these necessary functions. Currently the majority of USARIEM PCs use a program by Persoft named "Smart-Term 240" for this purpose.

An alternative method of TSMDBS access is via use of the Defence Data Network (DDN). DDN has three modes: Telnet, which allows remote logon to the USARIEM VAX; File Transfer Protocol (FTP), which facilitates file transfers; and Simple Mail Transfer Protocol (SMTP), which allows messages (mail) to be sent to other users on remote hosts.

HARDWARE:

The TSMDBS was initially implemented on USARIEM's DEC VAX-780 computer. Subsequently, the DEC 780 was replaced with a DEC VAX-6510. Currently the TSMDBS resides as a custom Oracle database application on the VAX-6510.

Access to the database has been accomplished with Intel-based PCs with either direct lines to the VAX-6510 or indirect access via modem and telephone line.

Communications and datalink technology is evolving rapidly. Data transfer via satellite-based or microwave link is becoming feasible, reliable, and more affordable. It will soon become possible and advantageous, to use such technology in upgrades to the TSMDBS in lieu of the current method of modems and direct wire links. One can anticipate that future versions of the TSMDBS, will allows users to access the database data entry screens and report generators via wireless palm size pen-based computers. This will increase the physical portability and convenience of the system and increase ease of use.

RELATIONSHIP TO THE P^2NBC^2-USARIEM SOLDIER PERFORMANCE DATABASE:

The P^2NBC^2-USARIEM Soldier Performance Database System was recently released for use by USARIEM scientists (Geo-Centers, 1994). This is an Oracle database that permits menu driven as well as ad hoc (using SQL-based commands or programs) search and analysis of a wide variety of measurements obtained from USARIEM research studies (Geo-Centers, 1992). The TSMD' S study summary and TS demographic information tables contain a number of data fields in common with similar descriptive tables in the P2NBC2-USARIEM Soldier Performance Database System.

Therefore, it should be feasible to incorporate the TSMDBS as a medical database subsystem within the P2NBC2-USARIEM Soldier Performance Database System. Integrating the physiologic and medical data would result in more realistic assessment of the medical consequences of environmental and other stresses that TSs are exposed to during the research studies.

RELATIONSHIP TO THE USAMRDC VOLUNTEER REGISTRY DATABASE:

The Human Use Review Office at the USAMRDC Headquarters in Frederick, Maryland instituted, in 1989, a database for registering individuals who participate in human use research studies at any of the USAMRDC research institutes, including USARIEM (USAMRDC, 1989). This database, implemented with the Oracle database development system by programmers at USAMRDC Headquarters has been distributed to USARIEM for local use. The TS data is periodically transfered from the USARIEM VAX to USAMRDC Headquarters. Currently the Chairperson of the USARIEM Quality Assurance Committee is responsible for the timely entry of data pertaining to volunteer TSs participating in USARIEM studies. Data entry is delegated by the Chairperson of the Quality Assurance Committee to a USARIEM enlisted soldier.

The USAMRDC Volunteer Registry Database tables are currently configured to collect basic TS demographic information and addresses; short summaries of the human use research studies, their USAMRDC identification number, and study period; reports of serious or unexpected adverse incident or reaction; and information about devices or materiel utilized in a particular study. Additional tables track the authorization and type of information released to the public or other agencies about USAMRDC TSs or research studies.

The USAMRDC Volunteer Registry Database is designed to support USAMRDC Headquarters administrative tracking and reporting requirements. The Volunteer Registry Database system, unlike the TSMDBS, does not incorporate features for real-time tracking of study and nonstudy TS medical problems for USARIEM and therefore cannot be utilized by USARIEM medical monitors or the NRDEC TSMO as an information and communications resource for the day-to-day tracking and coordination of test subject health and medical care. The test subject adverse

incident data for the Volunteer Registry Database is entered after the completion of a study whereas, in the TSMDBS, it is entered on site or at the clinic as soon as possible after it occurs. Additionally, the USAMRDC Volunteer Registry Database does not collect data on study related risks and procedures so that there are no means of determining rates of adverse incidence with respect to amount of risk exposure.

USER'S GUIDE

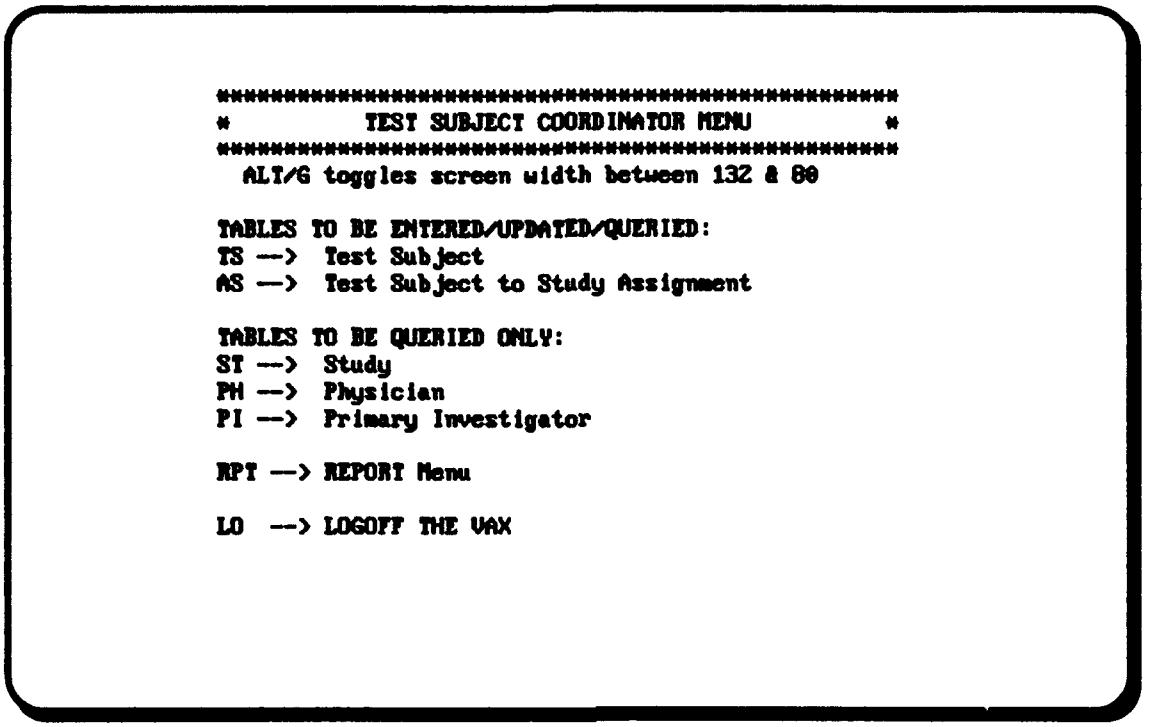
MAIN MENU:

The user enters the system in the manner prescribed by the database manager (see Appendix B). After logging into the TSMDBS, a menu screen is generated. The TSMO TSMDBS menu is depicted below. Subsequent selection menus illustrate how access to the TSMDBS is tailored for different user categories. Non-physician users have fewer items to select from because medically related menu items have been deleted from their menus.

```
**************************************************
*          TEST SUBJECT PHYSICIAN MENU           *
**************************************************

TABLES TO BE ENTERED/UPDATED/QUERIED:
HE --> Report of Medical History/Medical Examination
MH --> Report of Medical History
ME --> Report of Medical Examination
SP --> Soap
TS --> Test Subject

TABLES TO BE QUERIED ONLY:
ST --> Study
AS --> Test Subject Assignment
PH --> Physician
PI --> Primary Investigator

RPT --> REPORT Menu

 LO --> LOGOFF THE VAX
```

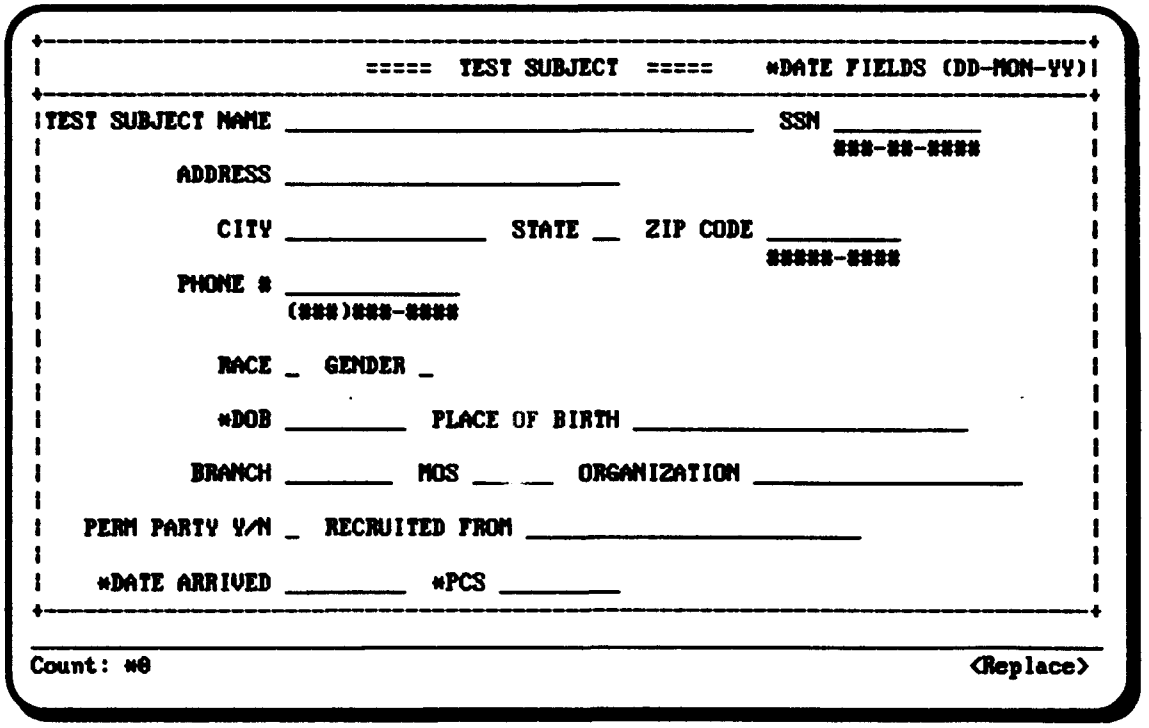
```
*******************************************
*          MEDICAL MONITOR MENU           *
*******************************************

TABLES TO BE ENTERED/UPDATED/QUERIED:
SP --> Soap

TABLES TO BE QUERIED ONLY:
TS --> Test Subject
ST --> Study
AS --> Test Subject Assignment
MH --> Report of Medical History
ME --> Report of Medical Examination
PH --> Physician
PI --> Primary Investigator

RPT --> REPORT Menu

 LO --> LOGOFF THE VAX
```

```
*************************************************
*          PRIMARY INVESTIGATOR MENU            *
*************************************************

TABLES TO BE ENTERED/UPDATED/QUERIED:
ST --> Study
TP --> Test Subject Procedures

TABLES TO BE QUERIED ONLY:
TS --> Test Subject
AS --> Test Subject Assignment
PH --> Physician
PI --> Primary Investigator

RPT --> REPORT Menu

 LO --> LOGOFF THE VAX
```



TEST SUBJECT DEMOGRAPHIC DATA ENTRY FORM:

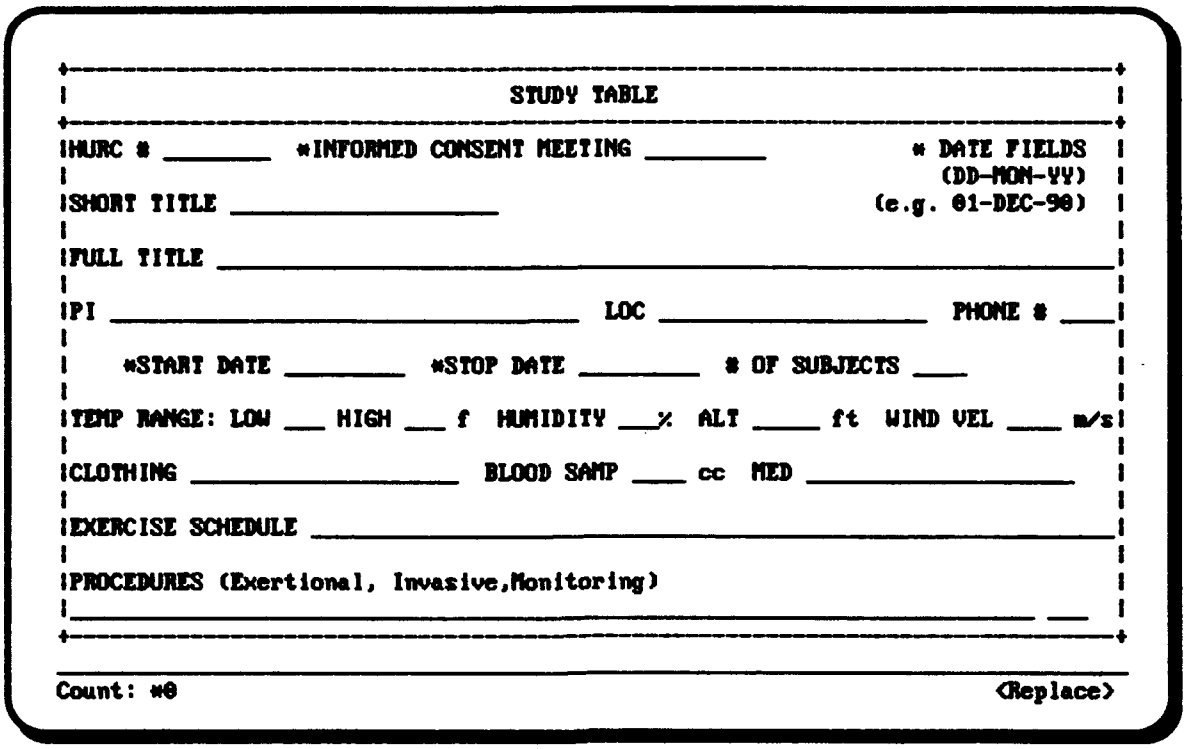
When a soldier initially reports for administrative processing as a Test Subject, the TSCoord enters, at her location (NRDEC environmental chamber building, across the street from USARIEM), basic TS demographic information into the TSMDBS. This is entered into the data fields of the computer form depicted below. Only the TSCoord can edit the fields in this form. This prevents duplication of key data elements such as TS names and social security numbers. The form can be used in either a data entry or data query mode. In the query mode, known data are entered in one or more fields. Wild card characters can also be utilized. The query is then activated by a specific series of keystrokes (see Appendix B for details), the database engine (kernal) then searches through previously entered TS records for TSs with data elements that match the entered query conditions. When in the query mode, the number of records retrieved meeting the desired criteria are indicated at the bottom of the screen and the user can page up or down (using the up or down arrow keys) to view each of the retrieved records.



The TS data entry screen provides data necessary for tracking a TS's address, age, and projected date for nonavailability. If there is a need, for example to send correspondence to TSs who participated in a particular study, a list of the test subjects and their addresses could be retrieved, saved to a text file, and printed. TSs' current ages calculated from the "DOB" field are automatically inserted into medical exam forms as discussed subsequently. This is an example of how data from different data entry forms can be interlinked.

STUDY SUMMARY DATA ENTRY FORM:

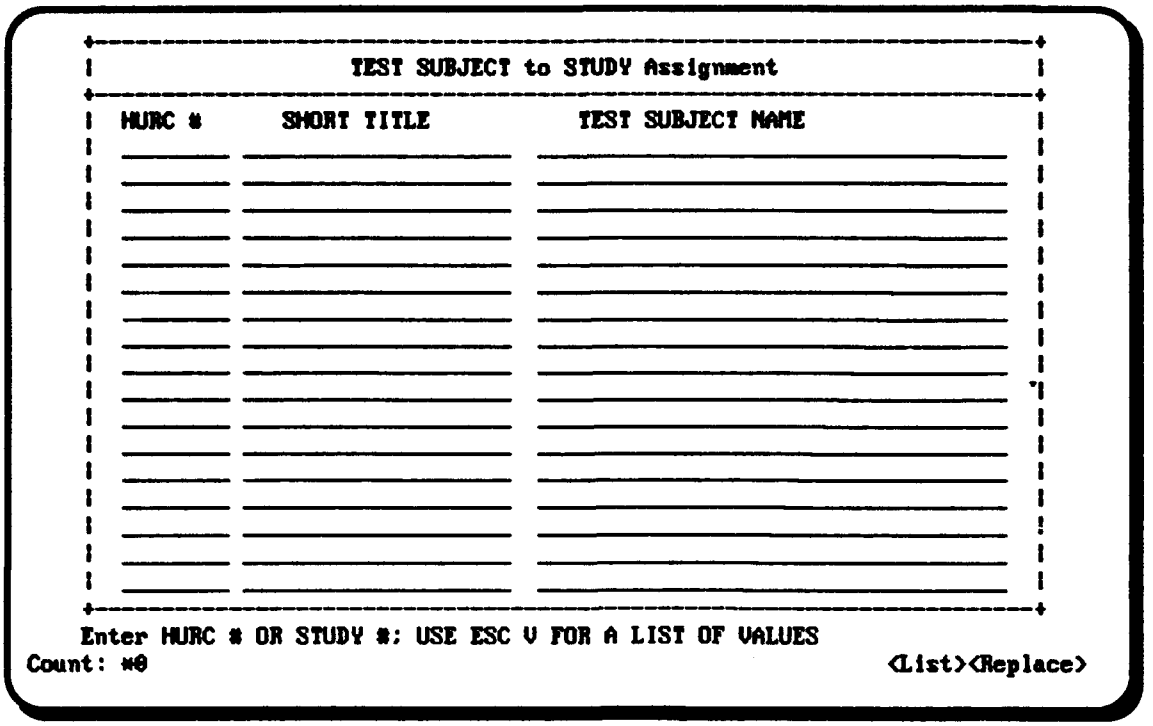
Test subjects are then assigned to specific studies. Before this can be done via the TSMDBS, basic information about the studies must be entered by the PIs or their assistants. The data entry screen for this purpose is depicted below:



The study summary data form above provides key pieces of information such as HURC number and start and stop dates. The HURC number, aa primary key, provides a unique and standardized identifier for a study. This allows unambiguous linkage of TSs with specific studies. The environmental parameters allow for retrieving summaries of studies that operated within specific environmental stress ranges. The short title name facilitates columnar data output that includes a nonnumerical identifier for studies.

ASSIGNMENT OF TEST SUBJECTS TO STUDIES:

After the basic information about TSs and studies are entered, the TSCoord can then assign specific TSs to studies. This is accomplished by use of the following data entry screen:



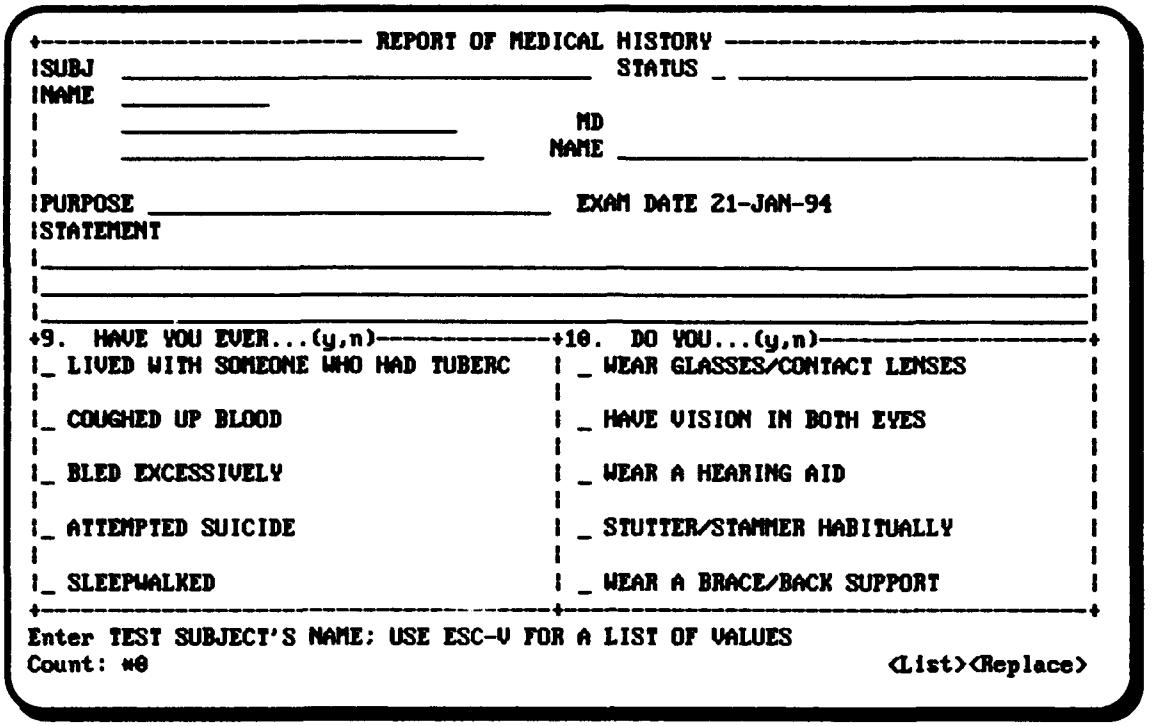
Only study numbers (HURC#) and TS names previously entered into the Study and Test Subject demographic information forms are allowed. As memory aids, popup picklists can be activated when in either the HURC# or TS Name fields. These lists are drawn from the Study Summary and Test Subject Demographics forms.

The next set of forms pertain to documenting TS medical assessments and study related risk exposures. The medical data entry forms are illustrated first, followed by the risk exposure forms.

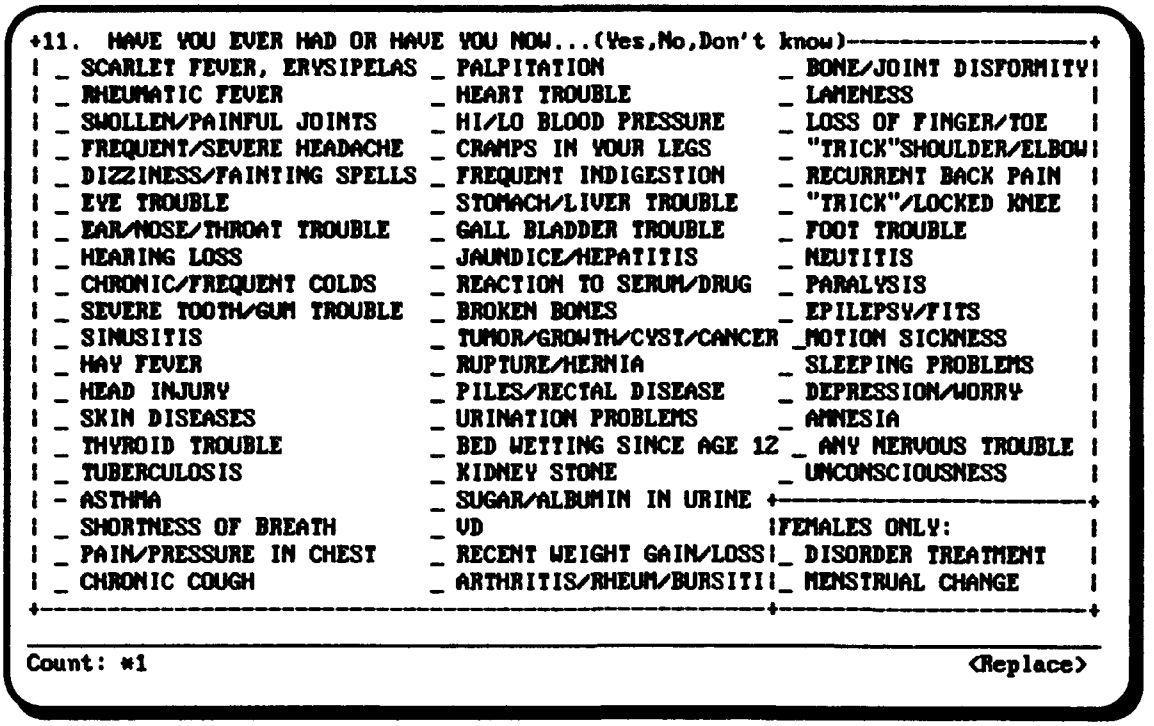
MEDICAL HISTORY DATA ENTRY FORMS:

The medical data entry forms include forms for the initial and periodic medical history and physical examination (Standard Forms 93 and 88) as well as a routine medical care data entry form for documenting day-to-day medical problems.

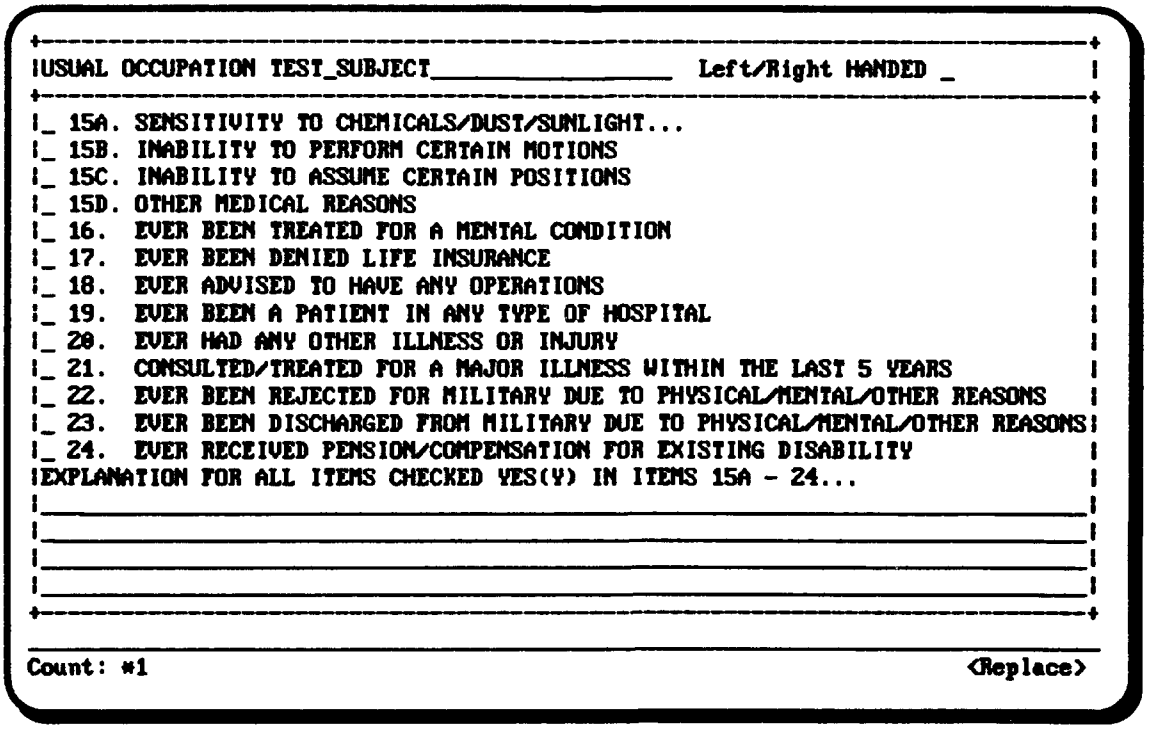
Below are the medical history and physical examination data entry screens:

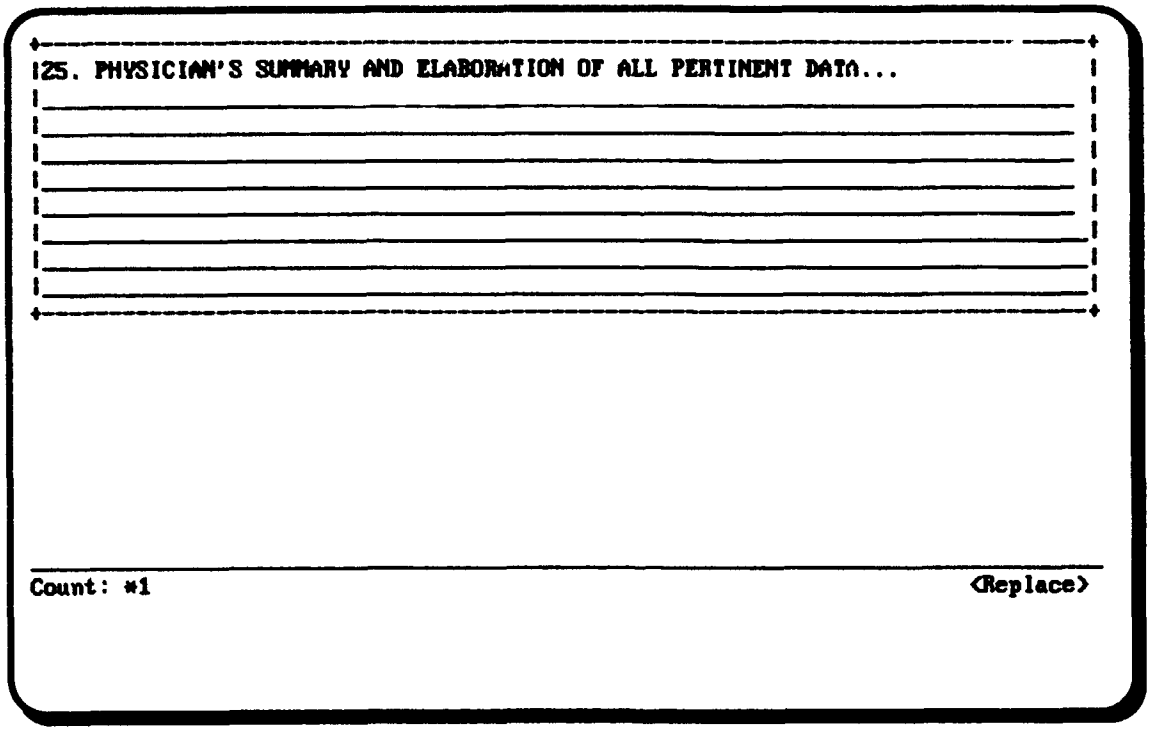


To initiate the medical data entry process the health care provider moves the cursor into the TS Name field and activates a TS name popup picklist. The appropriate name is selected. Similarly the health care provider's name is selected within the "MD Name" field. The answers to the questions are entered as either "Y", "N", or "D" for yes, no, or don't know. After completing this screen of information the user scrolls to the subsequent data screen:



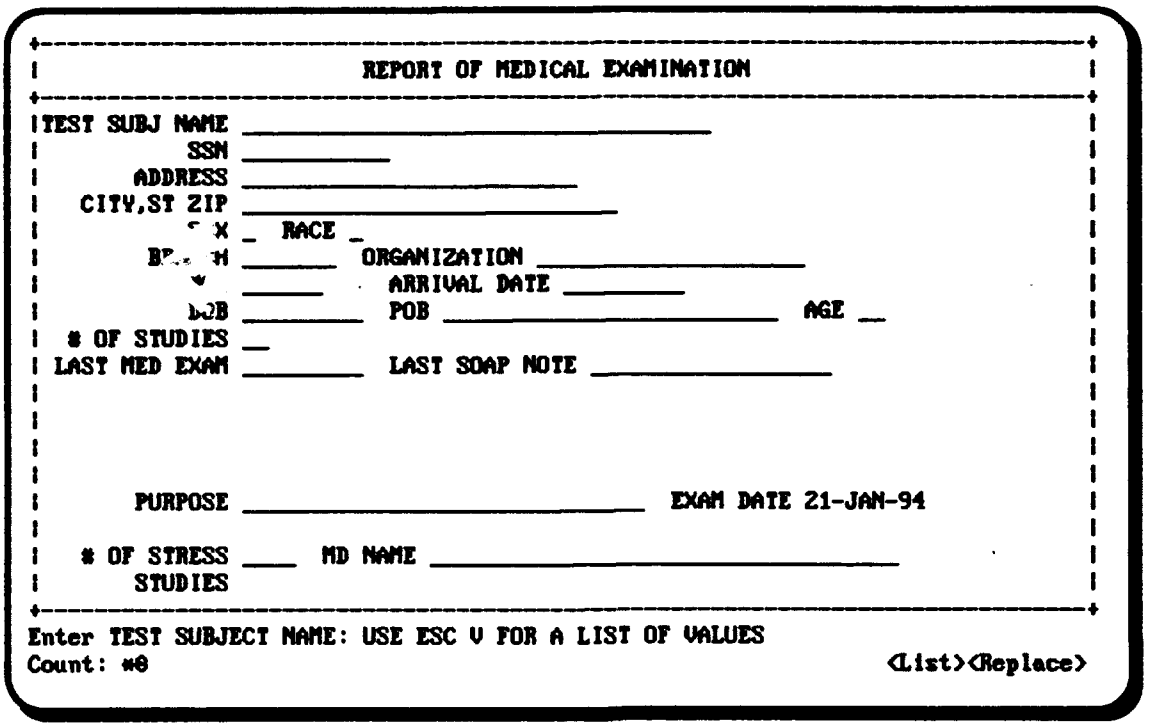
The data entry screen above replicates blocks 11 and 12 on SF 93. The remainder of SF 93 fields are on the following two data screens.





After elaborating on the positive elements of the medical history check list as illustrated above, the health care provider conducts the physical examination and enters the results into the medical examination data entry forms discussed in the following section.

MEDICAL EXAMINATION DATA ENTRY FORMS:



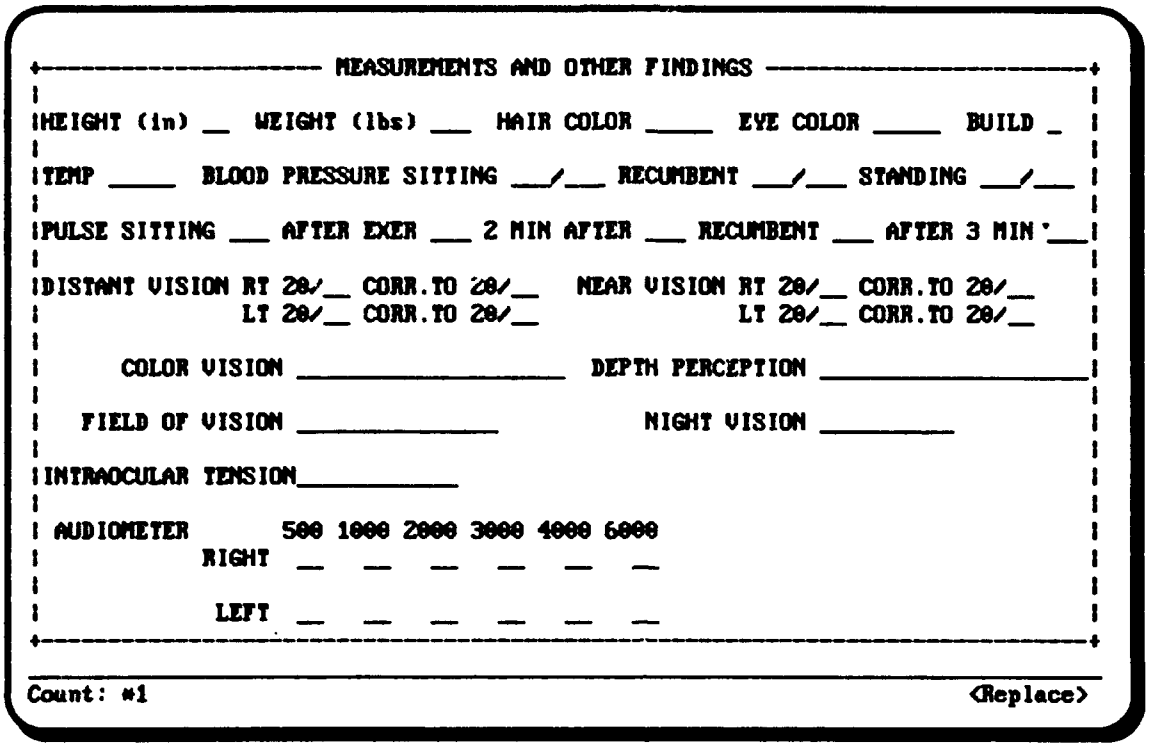
To start the data entry process, the health care provider moves the cursor into the TS name field and activates a TS name popup picklist. The basic demographic information is automatically retrieved from the TS demographic record as previously entered by the TSCoord. The field "# of Stress Studies" is automatically determined by a count variable that tracks the number of studies that the Test Subject has been assigned to since entry into the system. The MD (physician) name can be entered directly or chosen from a popup picklist. If an entered name does not exactly match that on the list, it is not accepted. This ensures that a query for exams done by a specific health care provider will not result in missing records due to a misspelled TS name.

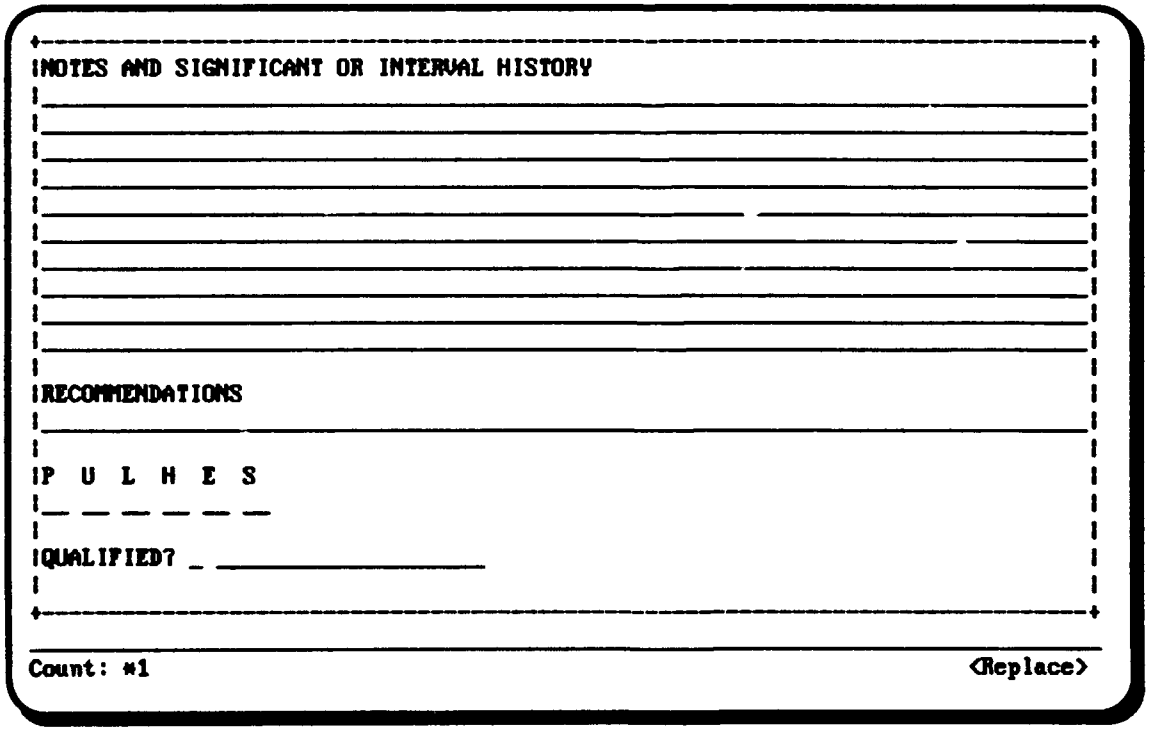
```
+-------------------------------------------------------------------------+
|      _ HEAD, FACE, NECK & SCALP     _ ABDOMEN & VISCERA                 |
|      _ NOSE                         _ ANUS & RECTUM                     |
|      _ SINUSES                      _ ENDOCRINE SYSTEM                  |
|      _ MOUTH & THROAT               _ G-U SYSTEM                        |
|      _ EARS-GENERAL                 _ UPPER EXTREMITIES                 |
|      _ DRUMS                        _ FEET                              |
|      _ EYES-GENERAL                 _ LOWER EXTREMITIES                 |
|      _ OPHTHALMOSCOPIC              _ SPINE, OTHER MUSCULOSKELETAL      |
|      _ PUPILS                       _ IDENTIFYING BODY MARKS, SCARS     |
|      _ OCULAR MOTILITY              _ SKIN, LYMPHATICS                  |
|      _ LUNGS & CHEST                _ NEUROLOGIC                        |
|      _ HEART                        _ PSYCHIATRIC                       |
|      _ VASCULAR SYSTEM              _ PELVIC (FEMALES ONLY)  _ HOW DONE? |
|                                     _ DENTAL                            |
+-------------------------LAB FINDINGS-------------------------------------+
|SPECIFIC GRAVITY _____  ALBUMIN _  SUGAR _  MICROSCOPIC NEGATIVE_________ |
|CHEST X-RAY RESULT                                                       |
|NIBH_____________________________________________________________________|
|SEROLOGY _____  HIV ___    _                                             |
|EKG _____________________________________      BLOOD_PRESSURE____/_____ |
+-------------------------------------------------------------------------+
Enter CLINICAL EVALUATION: (N)ormal, (A)bnormal, (NE)not_examined
Count: #1                                                        <Replace>
```

```
+------------------------- OTHER TESTS -------------------------------------+
|                                                                          |
|  CHEMISTRIES                        HEMATOLOGY                           |
|  _____ BUN                          ____ WBC                             |
|  _____ CREATININE                   ____ HCT                             |
|  _____ NA                           ____ HGB                             |
|  _____ K                             ___ PLATELETS (K)                   |
|  _____ CL                                                                |
|  _____ CO2                              DIFFERENTIAL                     |
|  _____ GLUCOSE                      ____ SEGS                            |
|  _____ URIC ACID                    ____ MONOS                           |
|  _____ CALCIUM                      ____ LYMPHS                          |
|  _____ PHOSPHATE                    ____ EOS                             |
|  _____ AST (SGOT)                   ____ BASOS                           |
|  _____ GGT                          ____ ATL'S                           |
|  _____ CPK                                                               |
|  _____ TOT BILI                      ___ SICKLE CELL                     |
|  _____ CHOLESTEROL                                                       |
|  _____ TRIGLYCERIDES                OTHERS?                              |
|                                     ____________________________________|
|                                                                          |
+-------------------------------------------------------------------------+
_________________________________________________________________________
Count: #1                                                        <Replace>
```

The data entry screen above augments the data blocks in the SF-88 to allow for reports and printouts of individuals with lab values within selected limits either for epidemiological tracking or to

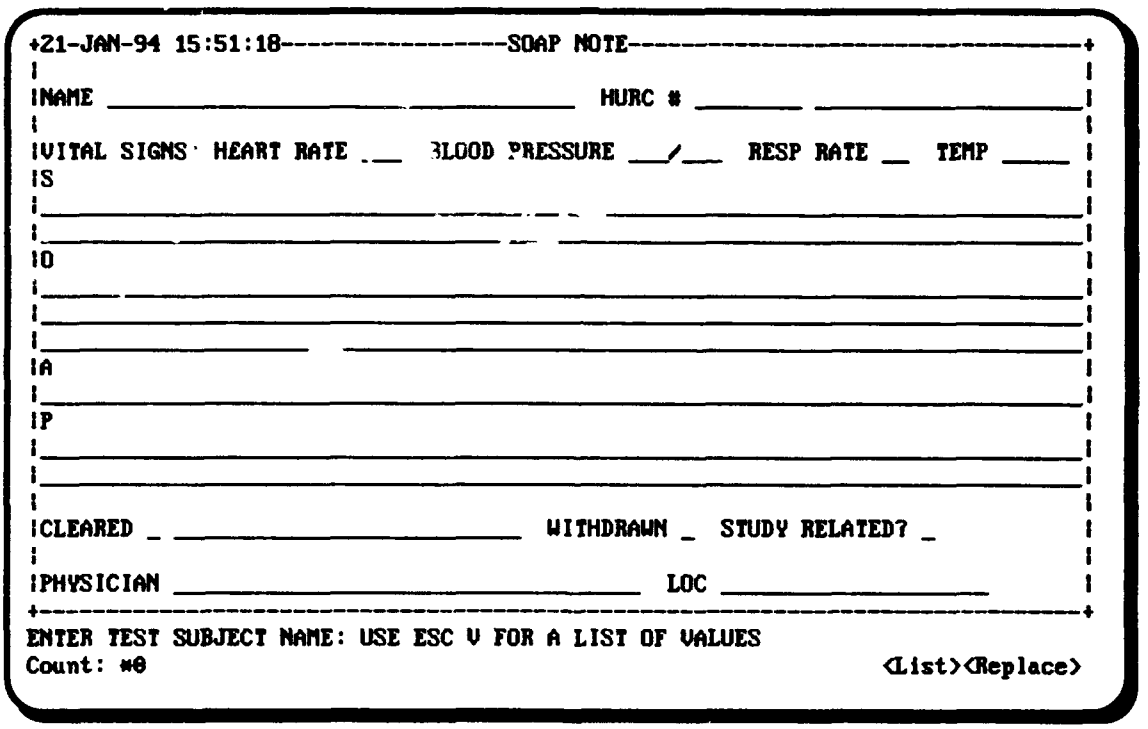
determine if abnormalities were explicitly detected and followed-up by comparing names with lab abnormalities and subsequent clinic notes.





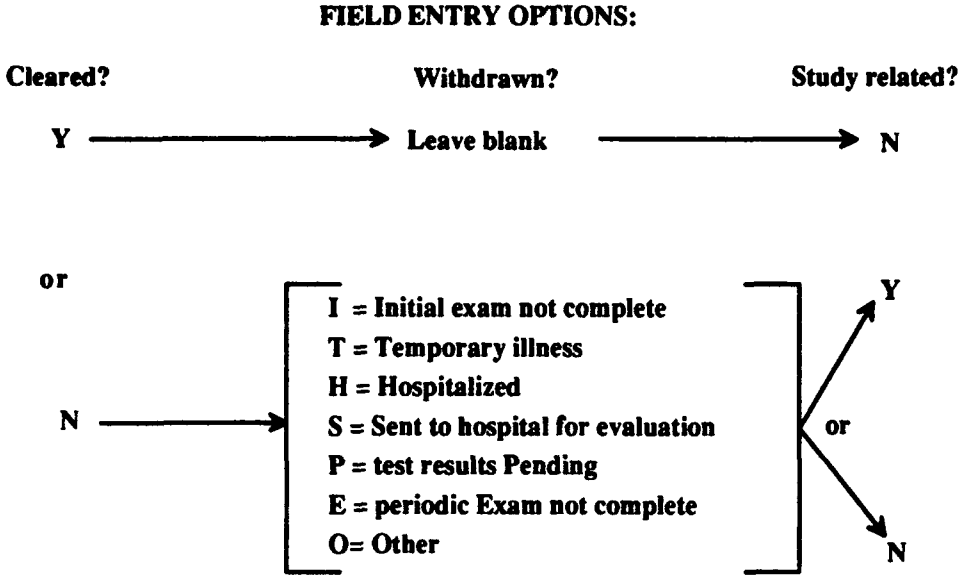
MEDICAL NOTE AND STUDY RELATED MEDICAL INCIDENT DATA ENTRY FORM:

The data entry form immediately above concludes the long form for physical examinations. The next medical data entry form below is the clinical encounter data entry screen. It is also called the "SOAP" note because it is arranged to sequentially describe a TS's symptoms (S) and history of present illness, the pertinent objective findings (O) from a focused physical exam and tests, the assessment (A) and diagnosis, and the plan (P) and disposition. This is a widely accepted method of structuring medical notes.



The date and time for the SOAP note are automatically entered. The TS, HURC#, and physician name are selected from popup picklists. The lookup values for TSs are limited to those assigned to a current study. After the TS name is selected, the study number and short study title to which he/she is currently assigned as well as the most current information for the "Cleared", "Withdrawn", and "Study related" fields are automatically filled in. Based on the results of the clinical assessment, the latter three fields may be changed. The values "Y" or "N" can be entered into the "Cleared" field. This indicates whether the TS is medically cleared to participate in USARIEM

research studies. Within the "Withdrawn" field, if the "Cleared" field is N, the physician may enter one of several options in the "Withdrawn" field as indicated below. The last field "Loc" indicates the

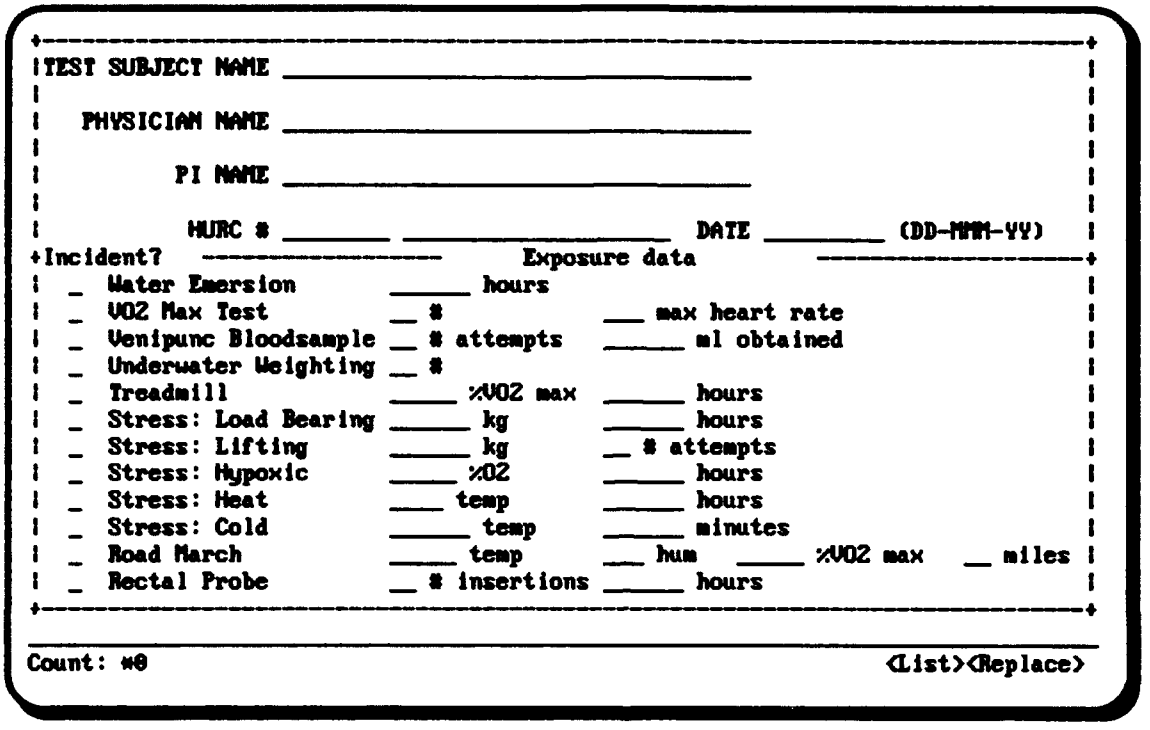


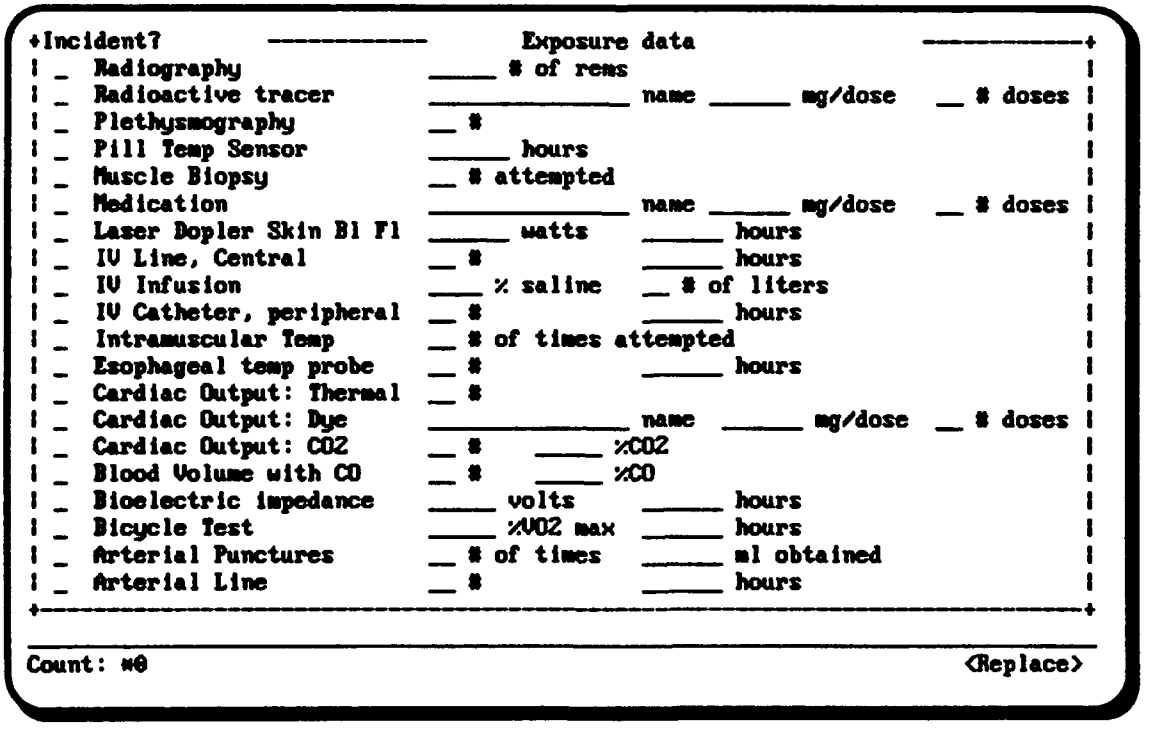
location where the TS was evaluated, e.g. clinic or test chamber area. This allows tracking of what problems are evaluated on site versus those cases seen at the clinic.

STUDY RELATED RISK EXPOSURE DATA ENTRY FORMS:

Now that the medical data entry forms have been illustrated, we proceed to the risk exposure data entry forms. The risk exposure data provides the basis for direct attribution of illnesses or adverse health events to study related exposures. Such information, for example could be of significant benefit to the HURC when estimating the risks associated with a proposed study. Such evaluations are currently often based on theoretical possibilities of risk. Although this is a valid means of assessing study related risks to TSs, objective data provided by the TSMDBS can be used to more accurately evaluate the magnitude of risks based on exposures that have actually resulted in adverse outcomes versus those that have not. This is particularly the case for theoretically minor risks that in fact commonly result in a significant number of adverse TS medical events.

The two parts of the medical incident and risk exposure data entry form shown below function in a similar manner to previously described forms. The TS, supervising physician, and PI names as well as the study number are selected from popup pick lists. The short study title and date are automatically filled in from related records.



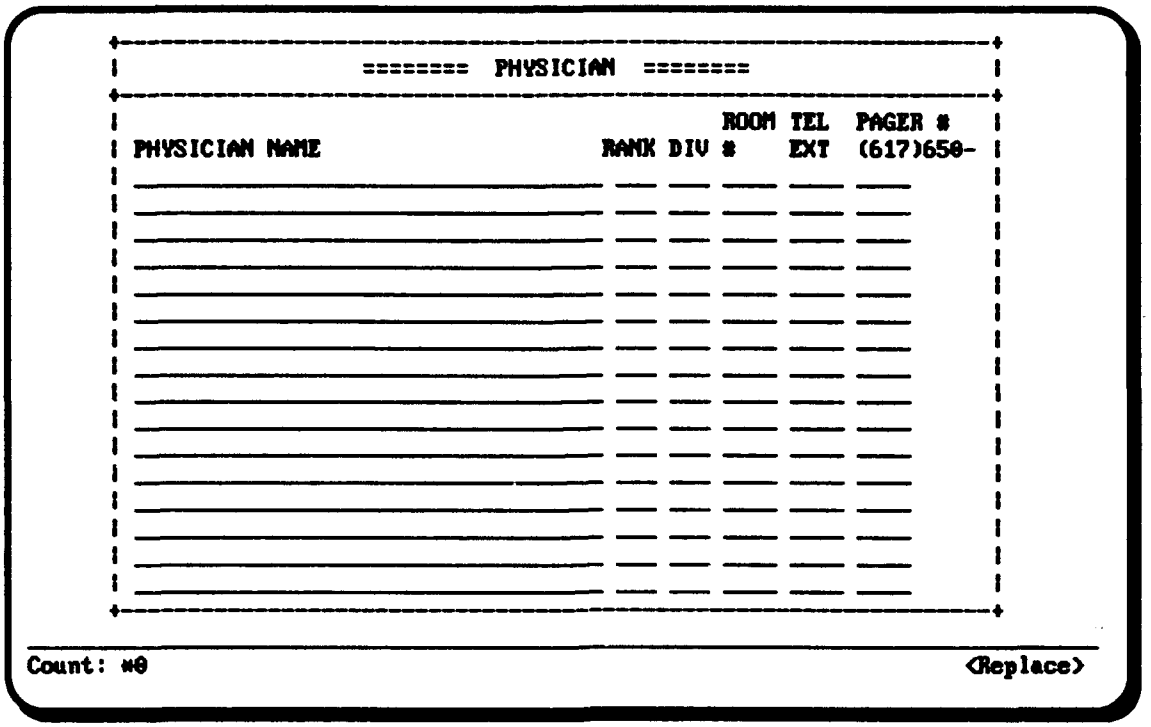


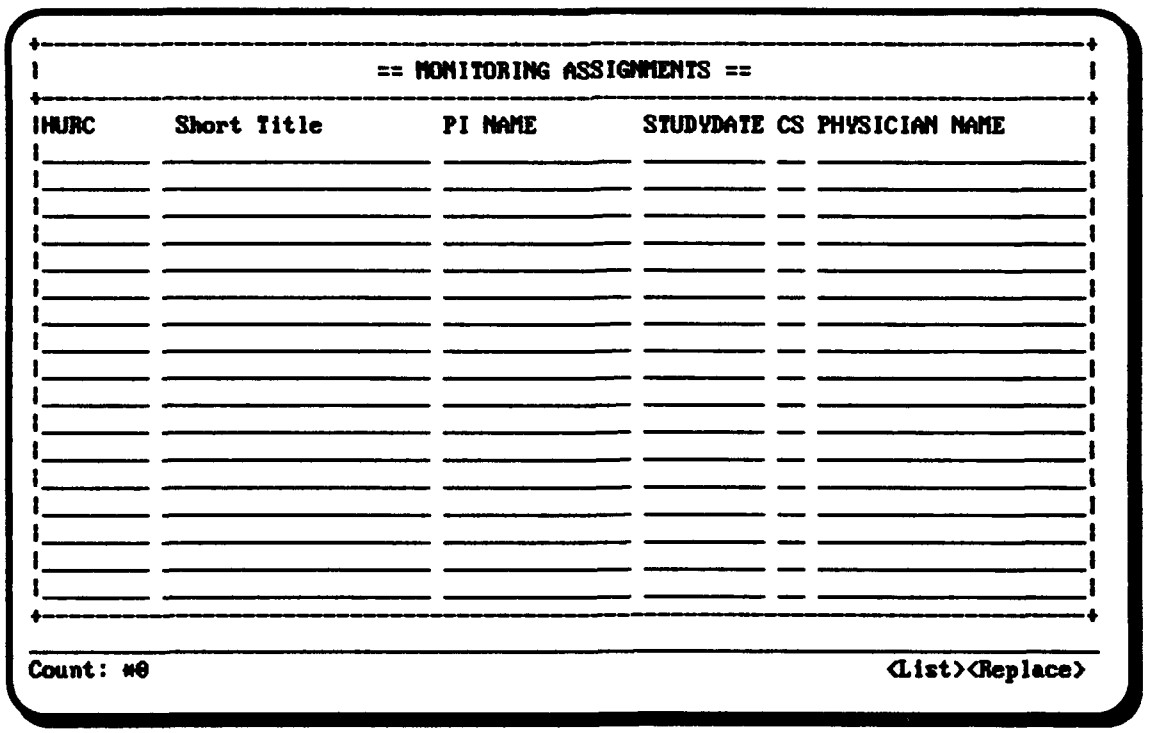
The items in the risk exposure portion of data entry forms were obtained from procedures listed in the USARIEM Type Protocol. The first data entry screen contains the most common exposures which avoids excessive paging back and forth between the two parts of this data entry form. It is intended that data be entered into these exposure quantification forms daily for each test subject participating in a study. This can be done by either the principal investigator or a designated assistant or technician. The data can then be easily updated or amended by using the form in a query mode to retrieve the previously entered risk exposure data for a particular TS. The database can be programmed to prevent editing of risk exposure data after a study has been completed as determined by the study completion date in the study summary record.

The first column of the form is used by either the medical monitor or principal investigator to indicate if a medical incident occurred related to that exposure. This enables reporting incidents by specific study, groups of studies, male versus female, age groups, etc. This information also provides "denominator data" so that incidence rates for adverse outcomes can be automatically calculated and reported. For example, the number of adverse study related incidents per number of hours of heat stress testing within a specified range of chamber temperatures, or number of adverse study related incidents per number of doses of a particular study related medication (e.g. pyridostigmine) could be calculated. Normally, each adverse study related incident is immediately reported to a medical monitor (who often is already on site). After evaluating and treating the test subject, the medical monitor types a medical note, via the medical note data entry form to describe the incident and the treatment, disposition, and change in study participation clearance, if any. A link between the incident and risk exposure record and corresponding medical note records is established via the date, TS name, and study number fields. This allows the database manager to program reports that lists assessments, treatments, and dispositions for incidents resulting from specific exposures.

PHYSICIAN DATA ENTRY FORM:

Medical monitor and other health care provider names and locations are entered into the physician table by the chief medical monitor. As currently designed, this is an essential data entry





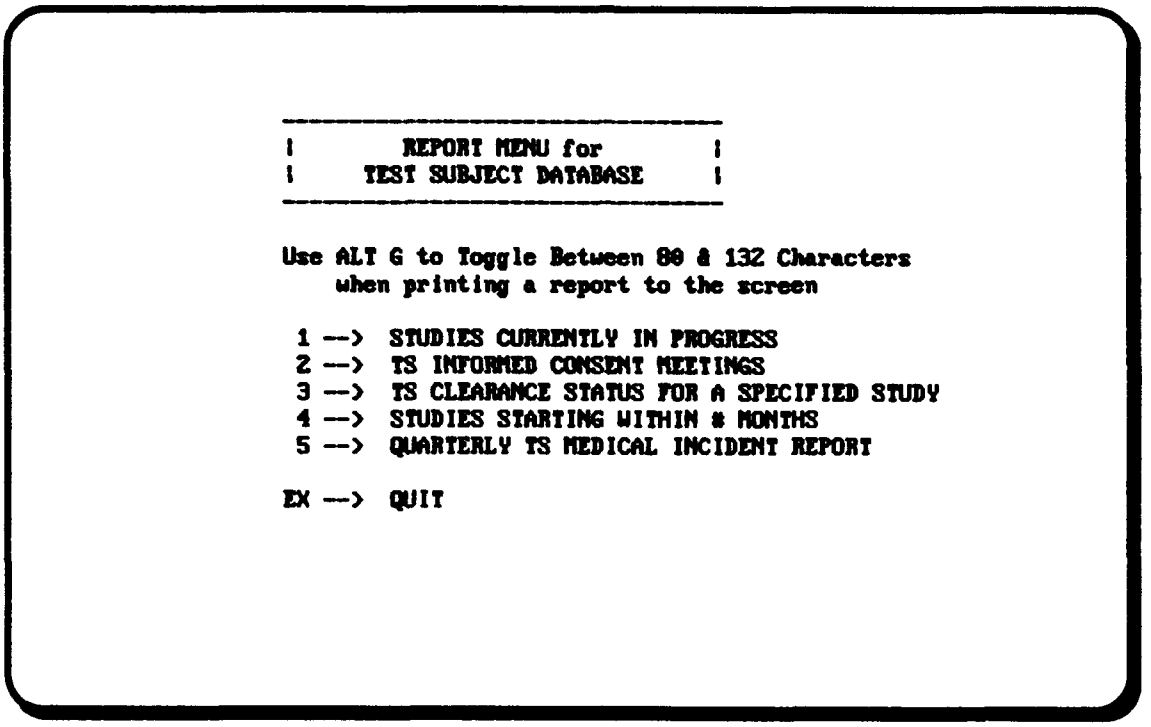
task because medical exam and medical notes cannot be saved without a physician name that matches a name in the physician information table.

ASSIGNMENT OF PHYSICIANS TO STUDIES DATA ENTRY FORM:

Following the physician data entry form is the medical monitor assignment data entry table. This links a primary medical monitor to each study. The study number or short title is selected from a popup picklist then the medical monitor is selected from a physician name popup picklist. This form can then be retrieved in nonedit mode by the medical monitors or principal investigators to inform who has responsibility to provide medical advisement and oversight for a particular study.

Although the computerized data entry forms described above are relatively few in number, they provide for the explicit tracking of many indicators of test subject health and availability. All the data entry forms can be utilized in a query mode. This is a powerful and easily learned method of using blank data entry screens with search criteria entered into the data fields of interest. This results in retrieval of records that satisfy the search criteria. Wild card characters can be used to facilitate setting broad search criteria. After the computer retrieves the records meeting the search criteria, the user can page up or down through all the retrieved records. This is useful for selected review or editing of previously entered data. Retrieving and processing data from multiple tables, however, requires database programming. This necessitates that the programmer have detailed knowledge of the structure of and interrelationships between the database tables as well as the field names. Most TSMDBS users, however, will not have the time or expertise to program complex SQL queries and statistical operations, or reports that provide the results of interlinked multi-table queries or complex processing. Therefore, commonly requested reports of this type are made available via a report selection menu. Below is an example of the current reports menu. This list can be expanded to serve specific information requirements of the various users Custom reports can be requested formally via the TSMDBS Development and Maintenance Committee or informally by users negotiating directly with the database system manager to define individualized report structures and appearances. The committee approach, although less flexible and more bureaucratic, is more likely to ensure that reports are standardized, satisfy legitimate defined and mutually agreed upon information requirements, are not idiosyncratic, and do not violate Test Subject confidentiality.

REPORTS MENU:



Report 1 lists all studies currently in progress, the study title, the principal investigator, the location of the study, and the assigned test subjects. Report 2 lists the dates for Test Subject informed consent meetings. Report 3 lists test subjects and their clearance status according to current studies. Report 4 lists summary data about current research studies. Report 5 provides a summary of study related medical incidents based on changes in TS clearances for studies conducted during the most recent quarter. These reports provide columnar data listings as illustrated in the simulated data screens below. Additional, more sophisticated reports can be added to the menu or submenus as required.

CURRENT STUDIES

SHORT TITLE	P.I.	LOCATION	TEL#	START	STOP
Cold Weather Boots	Endrusick	Arctic Chamber	x4567	2/5/90	4/16/90
Body Water Determination	Harmon	RM 222	x3456	1/89	5/23/90
Fibronectins and Heat	Dubos	Rm 328	x7891	2/12/90	5/01/90
Pyridostigmine & Endurance	Kolka	RM 213	x6785	3/3/90	4/23/90

TEST SUBJECT INFORMED CONSENT MEETINGS

DATE	P.I.	HURC#	TITLE
12 Oct 89	Young	4567	Salt Depletion and Heat Stress
15 Dec 89	Armstrong	3456	Exercise Induced Cutaneous Vasodilation
12 Feb 90	Pruzacyck	4989	Pyridostigmine Effects on Adaptation to Cold Water Emmersion
25 Mar 90	Stephenson	4783	Effects of Sleep Deprivation on Warm Weather Acclimatization
30 Jun 90	Mays	4651	Carbohydrate Loading for Endurance Exercise Testing

TS CLEARANCE STATUS

MURC# 3124
TITLE: Effects of Dehydration on Work Capacity
P.I.: Mike Sawka
Location: Tropic Chamber

TEST SUBJECT	CLEARED?
Bindewald, Mark	Y
Bradstreet, James	Y
Cutlip, Dennis	N
Hartman, Jeff	Y
Williams, Kevin	Y

June-Sept 90 TEST SUBJECT MEDICAL INCIDENT SUMMARY page 1

w= withdawn t=temporarily withdrawn n=evaluated & treated but not withdrawn
+ study related - not study related

MURC#	P.I.	# of TSs	Action		Notes
372	Moore	6	w	+	Metatarsal stress fracture
395	Stephenson	8	n	+	Slight hematochezia after passage of temperature pill.
403	Wenger	8	w	-	Metacarpal fracture
			t	+	Diaphragmatic discomfort
			t	+	Heat stress related nausea & vomiting
			n	+	Knee pain
			n	+	Knee pain
			n	-	Sinus headache
			n	+	Lower back pain
416	Stephenson	8	w	+	Contact dermatitis from methyl salicylate iodine
			w	+	Contact dermatitis from methyl salicylate iodine
			n	+	Contact dermatitis from methyl salicylate iodine
			n	+	Contact dermatitis from methyl salicylate iodine

TEST SUBJECT MEDICAL INCIDENT SUMMARY page 2

Total # of TSs: 30

	Study	Non-study	Total
Permanently withdrawn:	3	1	4
Temporarily withdrawn:	3	0	3
Evaluated but not withdrawn:	8	1	9
Total medical incidents	14	2	16

RESULTS

A trial of the TSMDBS lasted approximately two months. This trial demonstrated the feasibility of the TSMDBS. User testing confirmed the relative ease of gaining entry into the system via modem from the NRDEC clinic and environmental chambers as well as direct access via PCs in the USARIEM computer center. The most significant problems were related to poor compliance with data entry responsibilities, lack of user confidence in their computer skills, and lack of experience with the use of modems and database systems. Excessive delays in connecting to the VAX via modems as well as slow data access and transmission rates (2400 baud) were sources of significant user frustration. The data transaction delays were often a function of the number of individuals simultaneously using the DEC VAX 780. The subsequent changeover to the DEC VAX 6510 with higher processing speed and larger memory capabilities has greatly improved the database performance.

DISCUSSION

The TSMDBS was designed to improve the tracking of research study related risks and medical incidents as well as improve the coordination of medical care provided to test subjects by the physically dispersed and peripatetic NRDEC and USARIEM physicians. This database system was implemented on the USARIEM DEC VAX computer with the Oracle Professional Database Development System.

A trail run of the initial version of the TSMDBS proved that the system worked and was accessible from the USARIEM PC user center, the NRDEC clinic, as well as from the TSCoord's office in the NRDEC climactic chambers building. From the very beginning of the design process, it was anticipated that convincing the prospective users to enter their assigned shares of data into the system would be a major factor determining the success of the TSMDBS. There was indeed resistance to entering data into the TSMDBS despite considerable effort to facilitate the data entry by using the prevailing paper-based data collection formats as templates for the TSMDBS's computer screen data entry forms. Users were provided written instructions on the use of the TSMDBS and many users were also supported with personal tutorials.

Suggestions for further development and implementation include the following:

- Avoid wire-based modems by use of wireless links and palm-top or pen-based light weight and portable computers for the principal users (Roth, 1994).
- A palm size computer should integrate the TSMDBS with a PC based pager and messaging software package.
- Explore the feasibility of inserting the TSMDBS as a component of the P^2NBC^2-USARIEM Soldier Performance Database to eliminate redundancy in TS demographic information and study summary data.

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APPENDIX A: DATA FIELDS

UNITED STATES ARMY RESEARCH INSTITUTE OF ENVIRONMENTAL MEDICINE
TEST SUBJECT MEDICAL DATABASE SYSTEM

This database is comprised of many tables.

- * **Fields are mandatory to commit a record**
- % **Fields can be entered using list of values (ESC V)**

TESTSUB TABLE : RESPONSIBILITY OF TEST SUBJECT COORDINATOR (TSCOORD & TSMD)

	Field	Type	Description
*	TSNAME	CHAR(35)	Test Subject Name - Last, First Minit
*	SSN	CHAR(11)	Social Security Number ###-##-####
	ADDRESS	CHAR(25)	Home Address
	CITY	CHAR(15)	City
	STATE	CHAR(2)	State Abbrev.
	ZIP	CHAR(10)	Zip Code #####-####
	PHONE	CHAR(13)	Home Phone Number (###)###-####
	RACE	CHAR(1)	A:Asian, B:Black, C:Caucasian, H:Hispanic, O:Other
	SEX	CHAR(1)	F:Female, M:Male
*	DOB	DATE	Date of Birth
	MOS	CHAR(6)	MOS
	TDY	CHAR(1)	Permanent Party y/n
	RECRUIT	CHAR(25)	Place Recruited From
	ARRDATE	DATE	Date of Arrival
*	PCS	DATE	PCS Date

* **Fields are mandatory to commit a record**
% **Fields can be entered using list of values (ESC V)**

STUDY TABLE : RESPONSIBILITY OF PRIMARY INVESTIGATOR (PI)

	Field	Type	Description
*	HURC	CHAR(8)	Study or Hurc Number
	INFCON	DATE	Date of Informed Consent Meeting
*	RECAP	CHAR(20)	Short Title
*	TITLE1	CHAR(78)	Hurc Title
	TITLE2	CHAR(78)	Hurc Title Continuatin
*%	PINAME	CHAR(35)	Primary Investigator Name
*%	LOC	CHAR(20)	Location of Study
	TELNO	CHAR(4)	Telephone Extension
*	BDATE	DATE	Beginning Date of Study
*	EDATE	DATE	Ending Date of Study
	NUMSUB	NUMBER(4)	Number of Subjects in Study
	LTEMP	NUMBER(3)	Low Temperature of Study (F)
	HTEMP	NUMBER(3)	High Temperature of Study (F)
	HUMID	NUMBER(3)	Percent Humidity of Study
	ALT	NUMBER(5)	Altitude in Feet
	WIND	CHAR(4)	Wind Velocity (m/s)
%	CLOTH	CHAR(20)	Type of Clothing Used in Study
	BLOOD	NUMBER(4)	Amount of Blood to be Drawn (cc)
	MEDUSE	CHAR(20)	Medications to be used in Study
	SCHED1	CHAR(60)	Exercise Schedule
	SCHED2	CHAR(78)	Exercise Schedule Continuation
	SENS	CHAR(78)	Type of Sensors to be Used/Procedures

* **Fields are mandatory to commit a record**
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TESTSTUDY TABLE : RESPONSIBILITY OF TEST SUBJECT COORINATOR (TSCOORD)

	Field	Type	Description
*%	HURC	CHAR(8)	Hurc or Study Number
	RECAP	CHAR(20)	Short Title (fills in)
*%	TSNAME	CHAR(35)	Test Subject Name

PHYSICIAN TABLE

*	PNAME	CHAR(35)	Physician Name Last, First Minit
	RANK	CHAR(3)	Rank
	DIV	CHAR(3)	Division Code
	ROOM	CHAR(4)	Room #
	TELNO	CHAR(4)	Telephone Extension
	PAGE	CHAR(4)	Pager Telephone Number

PI TABLE

*	PINAME	CHAR(35)	Primary Investigator Name Last, First Minit
	RANK	CHAR(3)	Rank
	DIV	CHAR(3)	Division Code
	ROOM	CHAR(4)	Room #
	TELNO	CHAR(4)	Telephone Extension

LOCATION TABLE

*	LOCATION	CHAR(20)	Location of Study

* **Fields are mandatory to commit a record**
% **Fields can be entered using list of values (ESC V)**

SOAP TABLE : JOINT RESPONSIBILITY OF TEST SUBJECT PHYSICIAN AND MEDICAL MONITOR (TSMD & MEDMON)

	Field	Type	Description
	CURDATE	CHAR(9)	System Date (filled in)
	CURTIME	CHAR(8)	System Time (filled in)
*%	TSNAME	CHAR(35)	Test Subject Name
*%	HURC	CHAR(8)	Study or Hurc #
	RECAP	CHAR(20)	Short Title (fills in)
	HEART	NUMBER(3)	Heart Rate
	BP1	CHAR(3)	Blood Pressure
	BP2	CHAR(3)	Blood Pressure
	RESPRATE	NUMBER(2)	Respiratory Rate
	TEMP	NUMBER(3)	Temperature
	S1	CHAR(78)	Symptoms and history of present illness: line 1
	S2	CHAR(78)	" " " " " " line 2
	O1	CHAR(78)	Objective findings: line 1
	O2	CHAR(78)	" " line 2
	O3	CHAR(78)	" " line 3
	A	CHAR(78)	Assesment and diagnoses
	P1	CHAR(78)	Plans, treatment, and disposition: line 1
	P2	CHAR(78)	" " " " line 2
*%	CLEARED	CHAR(1)	Subject Cleared?
	WITHDR	CHAR(1)	Subject Withdrawn? W,T,N
	RELATED	CHAR(1)	Study Related? Y,N
%	PNAME	CHAR(35)	Physician Name
%	LOCATION	CHAR(20)	Location of Study

* **Fields are mandatory to commit a record**
% **Fields can be entered using list of values (ESC V)**

MEDHIST TABLE : RESPONSIBILITY OF TEST SUBJECT PHYSICIAN (TSMD)

	Field	Type	Description
	CURDATE	DATE	Current Date (fills in)
*%	TSNAME	CHAR(35)	Test Subject Name
	AGE	NUMBER(3)	Age (fills in-calculated from DOB field)
	SEX	CHAR(1)	F, M (fills in from test subject table)
	MED	CHAR(65)	Medications
	ALLER	CHAR(49)	Allergies
	PPD	NUMBER(3)	Packs of Cigarettes Smoked per Day
	PMH1	CHAR(74)	Past Medical History - line 1
	PMH2	CHAR(74)	Past Medical History - con't
	PE1	CHAR(74)	Physical Exam - line 1
	PE2	CHAR(74)	Physical Exam - line 2
	PE3	CHAR(74)	Physical Exam - line 3
	LAB1	CHAR(74)	Lab Findings - line 1
	LAB2	CHAR(74)	Lab Findings - line 2
	ECG	CHAR(34)	Electrocardiogram
	CXR	CHAR(34)	Chest X-ray
*%	CLEARED	CHAR(1)	Subject Cleared?

CLEARED TABLE

	Field	Type	Description
*	CLEARED	CHAR(1)	Clearance Code
*	CLEARED_DESC	CHAR(26)	Clearance Description
			C : CLEARED
			I : INITIAL EXAM NOT COMPLETE
			T : TEMPORARY ILLNESS
			S : SENT TO HOSPITAL FOR EVAL
			H : HOSPITALIZED
			P : TESTS PENDING
			E : PERIODIC EXAM NOT COMPLETE
			O : OTHER

ASSIGN TABLE (Cheif medical monitor or USARIEM Medical Advisor)

	Field	Type	Description
*%	HURC	CHAR(8)	Study or Hurc #
	RECAP	CHAR(20)	Short Hurc Title (fills in)
	PINAME	CHAR(35)	PI Name (fills in)
	BDATE	DATE	Beginning Study Date (fills in)
*	CALLSTATUS	CHAR(2)	Call Status - OC on call; OS on sight
*%	PNAME	CHAR(35)	Physician Name

APPENDIX B: TSMDBS User Instruction Summary Handout

On the following pages are the user instructions for logging onto the USARIEM VAX and accessing the TSMDBS. Also included are brief instructions for form-based queries, a reminder of the purposes of the TSMDBS, a break down of data entry resposibilities, and some additional information for printing and interfacing with a speadsheet.

These instructions sheets were reduced in size for the convenience of the user allowing them to be folded along a centerline and carried in a wallet or purse. An example of the reduced instructions follow the full size pages.

USAMIEM TS MEDICAL DBMS

LOG ON INSTRUCTIONS

1. Find a PC that can access the VAX (e.g. user center)

USERNAME: _____
PASSWORD: _____

2. Choose a data entry form from the menu.
3. Use the template and key combinations below to enter, edit, save, or query the data.

Desired Action	Key combo
Clear form/Rollback	ESC C
Count Query Hits	ESC 4
Delete Character	Delete
Delete Record	ESC D
Duplicate Field	ESC 1
Duplicate Record	ESC 2
Exit/Cancel	Control Z
List allowed field values	ESC V
Block Menu	ESC B
Next Field	Tab or Return
Next Primary Key Fld	ESC Tab
Print (to user center line printer)	ESC P
Redisplay page	ESC R
Scroll Left	ESC left arrow
Scroll Right	ESC right arrow
Show Function Keys	ESC K
Video toggle 80 or 132 char for wide reports	ALT G

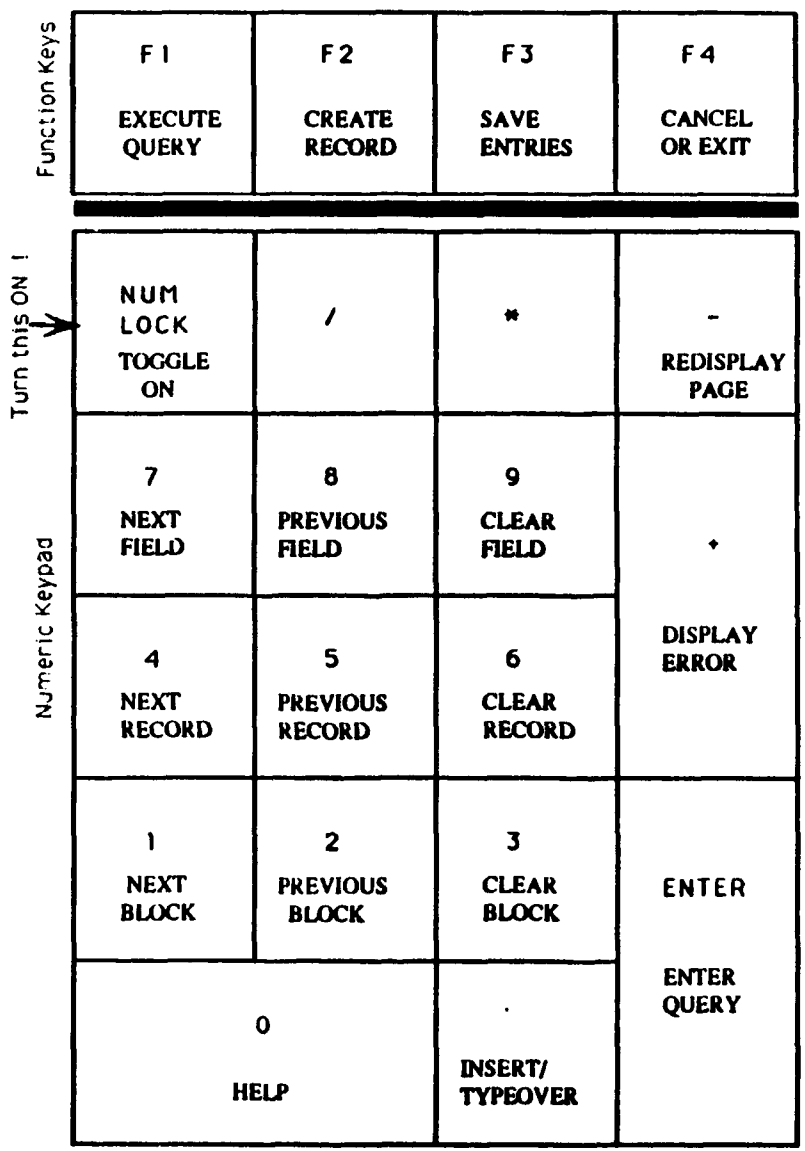
V1.0 1/91

Using the Query Mode:

1. Select the desired form.
2. Press the "ENTER QUERY" key.
3. Enter the query criteria in the appropriate fields (% = wildcard , & = SQL command line).
4. F1 activates the query &returns to edit.
5. Scroll thru the retrieved forms with the up and down arrow keys.
6. Edit fields & F3 to save edited forms .
7. Press F4 to return to the menu.

NB: Allow sufficient time for system to respond to cmds, system not as fast as a PC. Key combos are sequential not simultaneous

[For assistance contact: Donna Cardinal (x4842, rm 152) or Major Reardon (x4833, rm 146)]



USARIEM's TEST SUBJECT MEDICAL DATABASE SYSTEM

Purposes:
1. Day to day tracking of test subject (TS) medical problems.
2. Tracking of TS study related risk exposure.
3. Mechanism for reporting medical incidents.
4. Facilitate the medical screening and clearance processes.
5. Facilitate the selection of test subjects with the desired demographic profile.
6. Expedite the assignment of TSs to studies.
7. Facilitate the assignment of physicians to studies.
8. Improve awareness w.r.t. study start and completion dates.
9. Repository of quick summaries about studies.
10. Automatic generation of various medical and medical admin reports.
11. Other.

DATA ENTRY RESPONSIBILITIES

(caveat: if entering a batch of forms, commit each one separately by pressing F3 at the end of each form.)

TS Coordinator:
1. TS demographics.
2. Assignment of TSs to studies.
3. Timely updates to above.

TS Physician:
1. Initial, periodic, & special medical H&P
2. Medical assessment notes (SOAPs).
3. TS demographics if not done by above.

PIs (or designee):
1. Synopsis of study via the study form.
2. Timely updates to the study form .
3. TS procedure and risk exposure form.

USARIEM MDs:
1. Medical assessment notes (SOAPs)

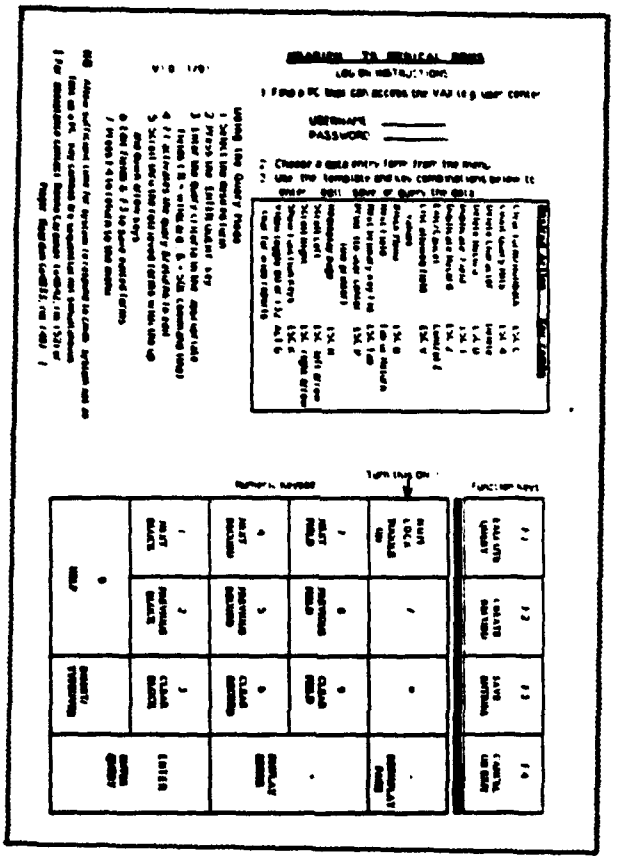
Medical Advisor:
1. Assignment of physicians to studies.
2. Medical assessment notes prn.
3. Updates to rosters & selection tables.

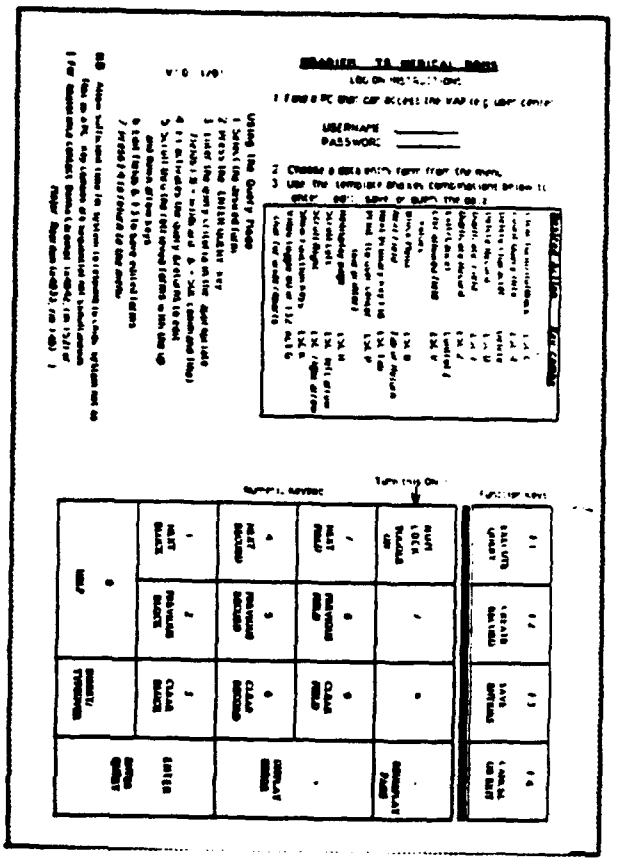
REPORTS & DATA QUERIES

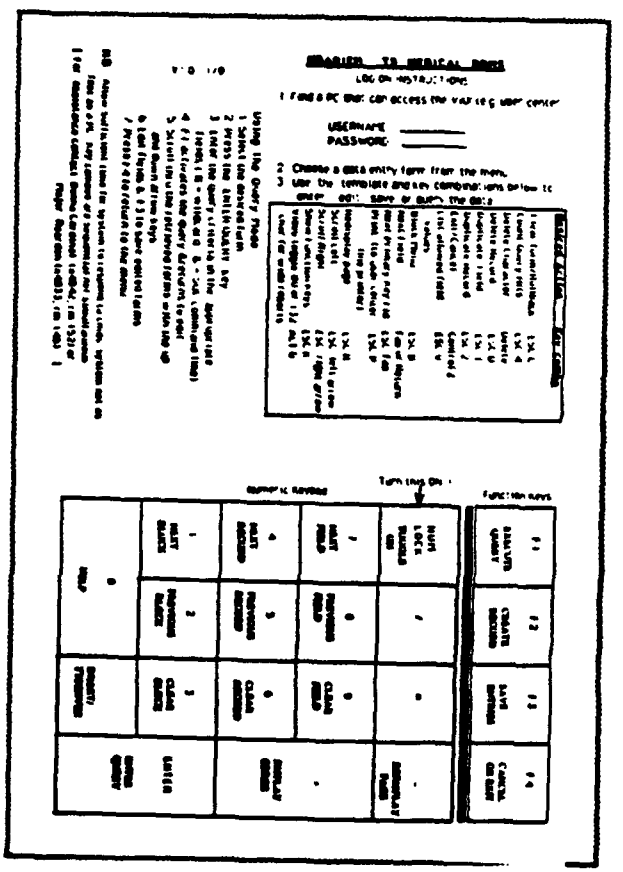
1. Each category of user will have standard reports available for viewing from the terminal. These can be selected from the initial menu.
2. Modified or custom reports can be designed upon request.
3. The query capabilities are very extensive, although you may need some practice or assistance from the system administrator (Donna Cardinal).
4. Only physicians can access the medical portion of the database.
5. Data can be down loaded to s2020, a VAX version of the Lotus 123 spreadsheet, this is a powerful and easy way to manipulate data in the database. To get into 2020 type s2020 from the VAX prompt, type t2020 for the 2020 tutorial.
6. Use the print screen key for local print outs of forms. The Oracle print sequence, esc p, routes the print job to a VAX print file that can then be printed on the USARIEM user center printers.

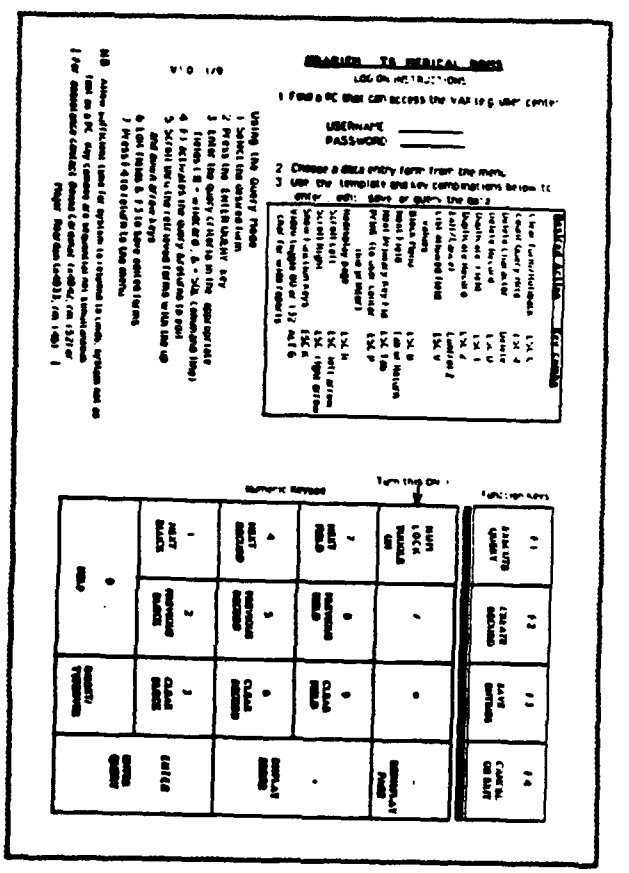
USARIEM TS MEDICAL DATABASE SYSTEM

Wallet or purse size cut out user aids









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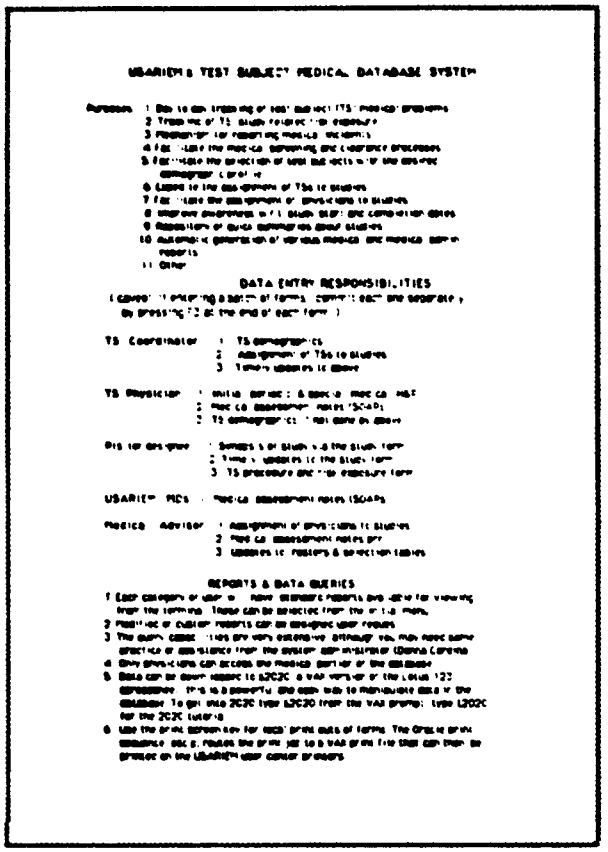

USARIEM's TEST SUBJECT MEDICAL DATABASE SYSTEM

Purposes: 1 Aid in the tracking of test subject (TS) medical problems
2 Tracking of TS study-related medications
3 Mechanism for reporting medical incidents
4 Facilitate the medical screening and clearance procedures
5 Facilitate the selection of test subjects with the desired demographic profile
6 Expedite the assignment of TSs to studies
7 Facilitate the assignment of physicians to studies
8 Improve awareness of all study start and completion dates
9 Repository of quick summaries about studies
10 Automatic generation of various medical and medical admin reports
11 Other

DATA ENTRY RESPONSIBILITIES

(Cannot proceed entering a batch of forms, commit each one separately by pressing F2 at the end of each form)

TS Coordinator: 1 TS demographics
2 Assignment of TSs to studies
3 Timely updates to above

TS Physician: 1 Initial physical & special medical H&P
2 Medical assessment notes (SOAP)
3 TS demographics if not done by above

PIs for designee: 1 Synopsis of study via the study form
2 Timely updates to the study form
3 TS procedure and risk exposure form

USARIEM PIDs: 1 Medical assessment notes (SOAP)

Medical Advisor: 1 Assignment of physicians to studies
2 Medical assessment notes pm
3 Updates to rosters & selection tables

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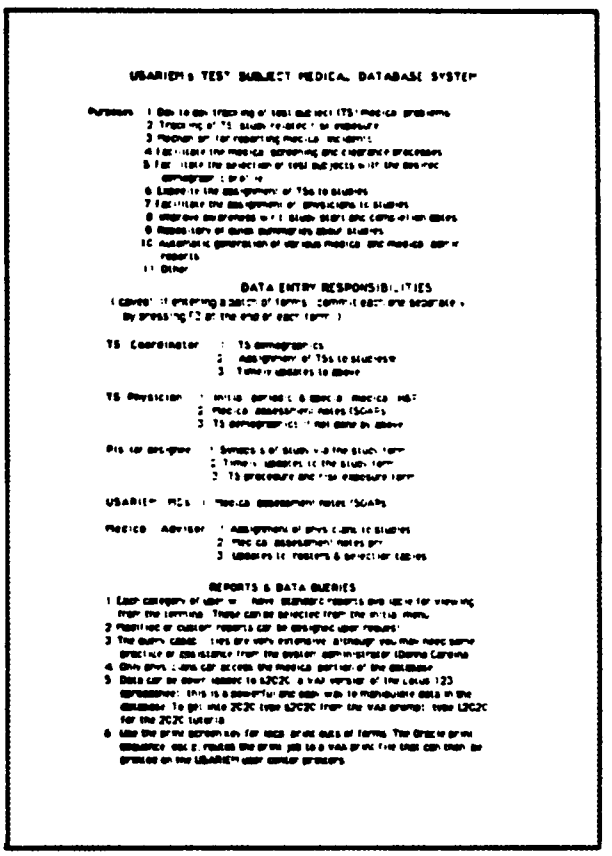

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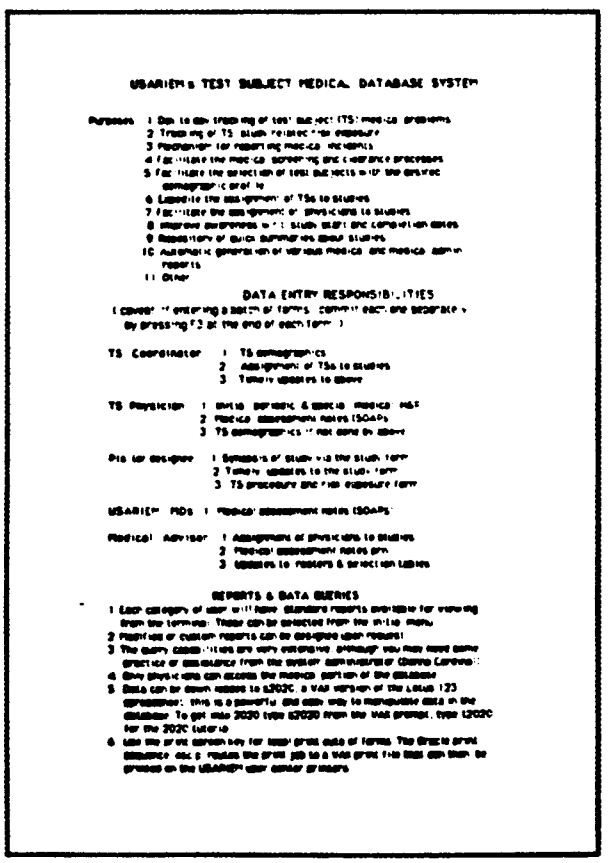

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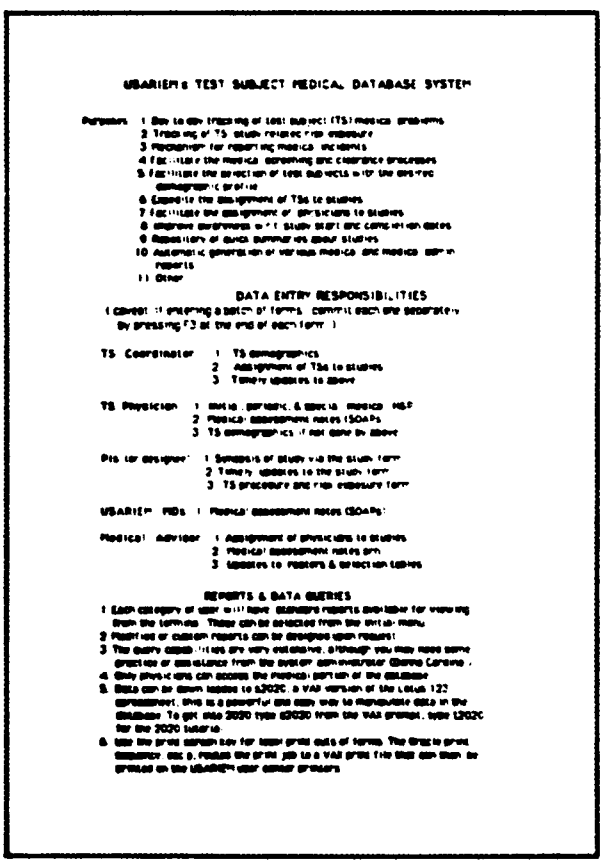

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Fort Detrick
Frederick, MD 21702-5009

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Fort Detrick
Frederick, MD 21702-5011

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The Pentagon, Washington, D.C. 20310

HQDA
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ATTN: DASG-ZA
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Falls Church, VA 22041-3258

HQDA
Office of the Surgeon General
ATTN: DASG-MS
5109 Leesburgh Pike
Falls Chaurch, VA 22041-3258

Commander
U.S. Army Aeromedical Research Laboratory
ATTN: SGRD-UAX-SI
Fort Rucker, AL 36362-5292

HQDA
Office of the Surgeon General
Assistant Surgeon General
ATTN: DASG-RDZ/Executive Assistant
Room 3E368, The Pentagon
Washington, D.C. 20310-2300

Dean, School of Medicine
Uniformed Services University of the Health Sciences
4301 Jones Bridge Road
Bethesda, MD 20814-4799

Commandant
U.S. Army Medical Department Center & School
Stimson Library
ATTN: Chief Librarian
Bldg. 2840, Room 106
Fort Sam Houston, TX 78234-6100

Commandant
U.S. Army Medical Department Center & School
ATTN: Director of Combat Development
Fort Sam Houston, TX 78234-6100

Director
U.S. Army Research Laboratory
Human Research & Engineering Directorate
ATTN: SLCHE-SS-TS
Aberdeen Proving Ground, MD 21005-5001

Commander
U.S. Army Military History Institute
ATTN: Chief, Historical Reference Branch
Carlisle Barracks
Carlisle, Pennsylvania 17013-5008

Commander
U.S. Army Natick Research, Development and Engineering Center
ATTN: SATNC-TM
U.S. Marine Corps Representative
Natick, MA 01760-5004